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Proposed Registration Decision PRD2017-11

Bifenthrin and Capture 240 EC

(publié aussi en français) **31 July 2017**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca

Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2017-11E (print version)
H113-9/2017-11E-PDF (PDF version)

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Overview

Proposed Registration Decision for Bifenthrin

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing cancellation of the registration of Bifenthrin Technical Insecticide and Capture 240 EC, containing the technical grade active ingredient bifenthrin. The use of bifenthrin on potatoes to control wireworm will be cancelled as of 31 December 2017. As the use on raspberries in British Columbia has been identified as a critical need in Canada, the PMRA is proposing registration for the sale and use of Bifenthrin Technical Insecticide and Capture 240 EC, for a period of three years to allow for the phase out of this use.

Bifenthrin Technical Insecticide (Registration Number 31395) and Capture 240 EC (Registration Number 31396) are conditionally registered in Canada. At the time of the original registration, the evaluation of the scientific information demonstrated that Capture 240 EC had value and that human health and environmental risk was acceptable. However, there remained some uncertainty with respect to the criteria for Track 1 classification under Canada's Toxic Substances Management Policy (TSMP). As such, additional information was required and a conditional registration was granted, but was limited to uses on potato and raspberry only, which were identified as critical needs by Canadian growers. The current applications were submitted to address the requested information and to convert Bifenthrin Technical Insecticide and Capture 240 EC from conditional registration to full registration.

The evaluation of the additional environmental information found that bifenthrin meets the criteria for Track 1 substances under the TSMP. The PMRA's implementation of the TSMP is outlined in Regulatory Directive DIR99-03.[1] This directive describes how Track 1 substances will be managed by the PMRA, and calls for the virtual elimination of Track 1 substances. For use of Capture 240 EC for control of weevils on raspberries, a phase-out period of three years is proposed. Since no suitable alternative exists for raspberries, the PMRA has determined that bifenthrin meets the critical need criteria as outlined in DIR99-03, which would allow for its use on a time-limited basis with the imposition of restrictions on the registration designed to minimize the risks associated with its use. Specific risk mitigation measures designed to minimize the risks include: limiting the use to a small geographical location (raspberries in British Columbia), buffer zones to minimize spray drift, vegetative filter strips to reduce runoff, and prohibiting application during crop blooming period. Therefore, registration for the use of Capture 240 EC on raspberries is granted for use only in British Columbia for three years beginning 1 January 2018 until 31 December 2020. The use of Capture 240 EC for control of wireworm on potato will be cancelled as of 31 December 2017.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of bifenthrin and Capture 240 EC.

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[1] Health Canada. DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy (TSMP)*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[2] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[3] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides and the assessment process, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on bifenthrin, the PMRA will consider any comments received from the public in response to this consultation document.[4] The PMRA will then publish a Registration Decision[5] on bifenthrin, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Bifenthrin?

Bifenthrin is an insecticide found in the commercial class product Capture 240 EC that is used to control wireworms in potatoes and several pests in raspberries, particularly those that are present at the time of harvest.

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[2] "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

[3] "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "… the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

[4] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

[5] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Bifenthrin Affect Human Health?

Capture 240 EC, containing bifenthrin, is unlikely to affect your health when used according to label directions.

Potential exposure to bifenthrin containing products may occur through the diet (food and water) or when handling, applying or entering treated areas. When assessing health risks, two key factors are considered:

- the levels where no health effects occur in animal testing, and
- the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, the technical grade active ingredient, bifenthrin, was of high acute toxicity by the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of low toxicity via the dermal route and slightly toxic via the inhalation route. Bifenthrin was non-irritating to the eyes and skin. Bifenthrin caused an allergic skin reaction.

The end-use product Capture 240 EC was of high acute toxicity via the oral route; consequently, the signal word and hazard statement "DANGER – POISON" are required on the label. It was of low toxicity via the dermal route, and of slight toxicity via the inhalation route. Capture 240 EC was minimally irritating to the eyes, slightly irritating to skin, and a potential dermal sensitizer based on a lack of acceptable sensitization test. Consequently, the signal work and hazard statement "POTENTIAL SKIN SENSITIZER", are required on the label.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as information from published scientific literature were collectively assessed for the potential of bifenthrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was neurotoxicity. There is some concern for increased sensitivity of the young exposed to bifenthrin. Data suggest that immature detoxification mechanisms in the young may lead to the accumulation of bifenthrin and increased toxicity at high levels of exposure.

The risk assessment protects against these and any other potential effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occur in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

Aggregate dietary intake estimates (food plus drinking water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most bifenthrin relative to body weight, are expected to be exposed to less than 34% of the acceptable daily intake. Based on these estimates, the chronic non-cancer dietary risks from bifenthrin are not of health concern for all population subgroups.

Acute dietary (food plus drinking water) intake estimates for the general population and all population subgroups were less than 75% of the acute reference dose, and are not of health concern. The highest exposed subpopulation was children 1-2 years old.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using bifenthrin on various crops and trials conducted on tea in India are acceptable.

For the listing of MRLs for this active ingredient on crop commodities, please refer to the Maximum Residue Limit Database in the Pesticides and Pest Management section of Health Canada's website.

Occupational Risks from Handling Bifenthrin

Occupational risks are not of concern when bifenthrin is used according to the label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Capture 240 EC as well as field workers re-entering freshly treated fields can come in direct contact with bifenthrin residues on the skin and/or through inhalation. Therefore, the label specifies that a long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and goggles must be worn during mixing, loading, application, clean up and repair. The label also requires that workers not re-enter treated fields for 12 hours after application except for hand harvesting of raspberries where workers cannot re-enter for 3 days. Taking into consideration these label statements, the precautionary measures, the number of applications and the expectation of the exposure period for handlers and workers, it was determined that the risks to these individuals are not a concern.

Risks in Residential and Other Non-Occupational Environments

For bystanders, exposure is expected to be much less than that for workers and the potential for drift from agricultural areas is expected to be minimal. Therefore, health risks to bystanders are not of concern. Applications are limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity, such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Environmental Considerations

What Happens When Bifenthrin Is Introduced into the Environment?

Bifenthrin meets the Government of Canada's criteria for a Track 1 Substance under TSMP. These criteria determine if a substance is toxic, takes a long time to break down and accumulates in living organisms. Because of these environmental concerns it is proposed that the registered use of bifenthrin on potatoes and raspberries be cancelled by 31 December 2017 and 2020, respectively. Interim risk reduction measures are proposed to further minimize environmental exposure during the phase out period.

Bifenthrin enters into the environment when applied as a foliar spray to raspberries and an in-furrow planting treatment to potatoes.

When bifenthrin is released into the environment, it can enter soil and surface water where it can persist under certain conditions. In soil, bifenthrin can be broken down slowly by soil bacteria. It binds strongly to soil particles, making it unlikely to move downward in the soil and reach groundwater. In aquatic environments, bifenthrin moves rapidly out of water and into sediment where it can persist. The vapour pressure and Henry's law constant of bifenthrin suggest that bifenthrin has low potential to volatilize from water and moist soil.

In the terrestrial environment, bifenthrin does not pose a risk to earthworms, birds, and plants; however, small mammals, beneficial insects, including bees, could be at risk if they come into direct contact or residues on plants. Precautionary label statements are required to inform users of the potential hazards to mammals and bees. The risk to bees can be reduced by restricting or prohibiting the application of bifenthrin during the crop blooming period.

In the aquatic environment aquatic plants are not at risk; however freshwater and marine fish and aquatic invertebrates are at potential risk on an acute and chronic basis. Spray buffer zones are required to protect aquatic organisms from spray drift. To reduce the risks of bifenthrin being carried in runoff to aquatic environments, in addition to precautionary label statements, a mandatory requirement for the construction and maintenance of a 10-metre vegetative filter strip between the area of application and waterbodies is required.

The persistency and bioaccumulation characteristics of bifenthrin were both above and below the cut-off values for the criteria for Track 1 substances under the TSMP. Therefore, PMRA requested additional environmental data to examine accumulation of bifenthrin by aquatic organisms through diets and to further characterize bifenthrin's behaviour and risks in the environment. The PMRA also requested other environmental data identified by the European Commission (2012).

Bifenthrin has the potential to accumulate in the tissues of organisms through various routes of exposures to levels that could cause effects. Characteristics such as persistence, accumulation in animal tissues and effects suggest that bifenthrin may be of concern if animals are exposed over a long period of time. Based on the available environmental information, PMRA concluded that bifenthrin meets the Government of Canada's criteria for a Track 1 Substance under the TSMP adopted in 1995. These criteria are also outlined in the *Persistence and Bioaccumulation Regulations* (SOR/2000-107) which are used to define persistent or bioaccumulative under sections of the *Canadian Environmental Protection Act* (CEPA, 1999). Under TSMP, substances meeting these criteria (Track 1) are persistent, bioaccumulative, toxic and primarily the result of human activity. Track 1 substances are targeted for vitual elimination from the environment, but may be registered for a limited time in exceptional circumstances (for example: critical need). The critical need for bifenthrin on raspberries for pre-harvest control in British Columbia continues to exist as there are no suitable alternatives. The need for bifenthrin on potatoes is not considered critical as alternatives are now registered. It is proposed that the registered uses of bifenthrin on potatoes and raspberries be cancelled by 31 December 2017 and 2020, respectively, because of these environmental concerns. Interim risk reduction measures are proposed to minimize environmental exposure during the phase out period.

Value Considerations

What Is the Value of Capture 240 EC?

Capture 240 EC controls wireworms, which are a major pest of potatoes, and several insects that are harvest contaminants in raspberries.

When Capture 240 EC was registered in 2014, Canadian growers identified a soil application at the time of planting to control wireworms in potato as a high priority. Since then, a new product containing phorate has provided growers with an additional management tool for wireworms.

Canadian growers identified a need for pre-harvest control of weevils and lepidopteran larvae in raspberries at the time that Capture 240 EC was first registered. There continues to be zero tolerance for insect harvest contaminants in raspberries and no suitable alternatives available to control weevils, the most prevalent contaminant. As such, foliar application of Capture 240 EC prior to harvest is considered to be critical for the management of insect contaminants of raspberries in British Columbia.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Capture 240 EC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with bifenthrin on the skin or through inhalation of spray mists, anyone mixing, loading and applying bifenthrin and performing cleaning and repair activities must wear long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and goggles. In addition, standard label statements to protect against drift during application are present on the label.

Environment

- Environmental hazard statements for bees, beneficial insects, small mammals and aquatic organisms are required.
- To reduce risk to pollinators, application is prohibited during the crop blooming period.
- Spray buffer zones ranging from 10 to 75 metres for non-target aquatic habitats are required. For all ground field sprayer use restrictions include the use of low drift air induction nozzles only, a minimum ASAE (American Society of Agricultural Engineers) medium spray quality and a wind speed restriction at the time of application (<8 km/hr).
- To reduce the potential for runoff of bifenthrin to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted, are required. In addition, a minimum 10-metre vegetative filter strip between the treatment area and the edge of a water body is required to reduce runoff of bifenthrin to aquatic environments.

Value

- Limit the use of Capture 240 EC to raspberries grown in British Columbia for a period of three years.

Next Steps

Before making a final registration decision on bifenthrin, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document).

The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

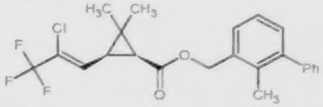
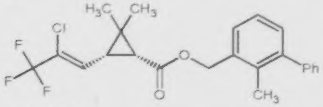
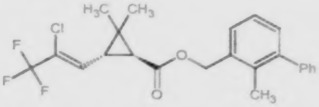
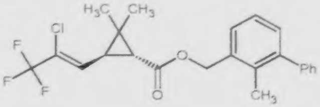
When the PMRA makes its registration decision, it will publish a Registration Decision on bifenthrin (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Bifenthrin

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substances	Bifenthrin and its trans isomer
Function	Miticide/Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	*bifenthrin:* (2-methylbiphenyl-3-yl)methyl (1*RS*,3*RS*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropanecarboxylate *trans isomer:* (2-methylbiphenyl-3-yl)methyl (1*S*,3*R*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropanecarboxylate *or* (2-methylbiphenyl-3-yl)methyl (1*R*,3*S*)-3-[(1*Z*)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2,2-dimethylcyclopropanecarboxylate
2. Chemical Abstracts Service (CAS)	*bifenthrin:* cyclopropanecarboxylic acid, 3-[(1*Z*)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethyl-, (2-methyl[1,1'-biphenyl]-3-yl)methyl ester, (1*RS*,3*RS*)- *trans isomer (double bond geometry unknown):* cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-, (2-methyl[1,1'-biphenyl]-3-yl)methyl ester, trans- (9Cl)
CAS number	82657-04-3 (bifenthrin) 83322-02-5 (trans isomer)
Molecular formula	$C_{23}H_{22}ClF_3O_2$
Molecular weight	422.88
Structural formula	bifenthrin:  *or*  trans isomer:  *or* 
Purity of the active ingredients	95.5%

1.2 Physical and Chemical Properties of the Active Ingredients and End-Use Product

Technical Product—Bifenthrin Technical

Property	Result
Colour and physical state	Off-white solid
Odour	Fluoro-chloro like smell
Melting range	66.6-69.0°C
Boiling point or range	N/A
Density	1.316 g/cm^3
Vapour pressure at 25°C	2.413×10^{-5} Pa
Henry's law constant at 20°C	1.01×10^{-4} atm m^3/mol 1/H = 9901 mol/ atm m^3
Ultraviolet (UV)-visible spectrum	λmax = 250 nm, ε = 3282.9 no absorption was observed above 300 nm.
Solubility in water at 20°C	pH — Solubility (μg/L) 4.05 — <1 7.18 — <1 9.20 — 3.76
Solubility in organic solvents at 20°C (g/L)	Solvent — Solubility Methanol — 48.0±0.7 Xylene — 556.3±29.3 Acetone — 735.7±47.2 1,2-dichloroethane — 743.2±16.4 Ethyl acetate — 579.8±47.2 n-heptane — 144.5±9.0
n-Octanol-water partition coefficient (K_{ow})	log K_{ow} = 8.0 at 20°C
Dissociation constant (pK_a)	Practically insoluble in water and no dissociable groups
Stability (temperature, metal)	Thermally stable at >200°C. No corrosion to phenoxy resin lined HDPE or steel. It is subject to photo-degradation in an aqueous environment. Isomer conversion and ester cleavage are very slow under natural sunlight without a photosensitizer.

End-Use Product—Capture 240 EC

Property	Result
Colour	Straw yellow
Odour	Mild naphthenic odour

Property	Result
Physical state	Liquid
Formulation type	Emulsifiable concentrate
Guarantee	240 g/L
Container material and description	Fluorinated HDPE bottle, 2.5-5 L
Density	0.954 g/ml
pH of 1% dispersion in water	4.6
Oxidizing or reducing action	The product does not contain any oxidants or reductants.
Storage stability	The product is stable to fluorinated HDPE bottles for 2 years under ambient temperature.
Corrosion characteristics	The emulsifiable concentrate is compatible with glass and fluorinated plastic containers.
Explodability	Non-explosive

1.3 Directions for Use

Potato
One in-furrow application of Capture 240 EC applied at planting at a rate range of 2.0–3.4 g a.i./100 m row (222–337 g a.i./ha) controls wireworms in potatoes, with low application rates for use under light to moderate pest pressure and high application rates for heavy pest pressure.

Raspberry
Foliar application of Capture 240 EC at a rate of 112 g a.i./ha controls obliquebanded leafroller, orange tortrix, black vine weevil, obscure root weevil, clay coloured weevil and earwigs in raspberries. One application may be made pre-bloom and a second may be made post-bloom with a minimum re-application interval of 30 days. A maximum of 224 g a.i./ha may be applied per year.

1.4 Mode of Action

Bifenthrin is a pyrethroid in the Insecticide Resistance Action Committee Mode of Action (MOA) Group 3A. Bifenthrin interferes with sodium channels within nerve cell membranes of insects, causing paralysis and death. This active ingredient acts by contact or ingestion.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Bifenthrin Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredient in the formulation have been validated and assessed to be acceptable for use enforcement analytical methods.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media.

Gas chromatography methods with electron capture or mass spectrometric detection (GC-ECD; GC-MSD; Methods P-0757/P-1073 in plant matrices and Methods P-1031 (Revised), R-1843M (Revised) and RAN-0204M in animal matrices) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70-120%) were obtained in plant and animal matrices. The proposed enforcement methods were successfully validated in plant and animal matrices by an independent laboratory. Extraction solvents used in the method were similar to those used in the metabolism studies; thus, further demonstration of extraction efficiency with radiolabelled crops was not required for the enforcement method.

Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Bifenthrin is a synthetic Type I pyrethroid insecticide. Synthetic pyrethroids induce neurotoxic effects primarily by binding to voltage-dependant sodium channels in neurons. Binding to the receptor delays closing of sodium channels, causing the depolarization of neurons. This affects action potentials and results in repetitive activity. Type I pyrethroids, such as bifenthrin, typically induce "T-syndrome" which is characterized by rapid onset of aggressive behavior, increased sensitivity to external stimuli, fine tremor, prostration with coarse whole body tremor, elevated body temperature, coma, and death.

A detailed review of the toxicological database for bifenthrin was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The majority of the submitted studies were carried out in accordance with accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is acceptable and the database is considered adequate to define the majority of toxic effects that may result from exposure to bifenthrin. The database was supplemented by published scientific literature studies.

Metabolism and toxicokinetics were investigated using radiolabelled bifenthrin in standard single low- and high-dose, as well as repeated low- and high-dose oral gavage studies in rats. In addition to these studies, a longer term study was conducted in which female rats were dosed with bifenthrin for 70 days, followed by an 85 day period without dosing. Absorption was low. Most of the administered dose was recovered within 48-72 hours of dosing, with negligible amounts of radioactivity in expired air. The majority of test material was excreted in the feces (25-96%) as unchanged bifenthrin and metabolites. In bile duct cannulated rats, biliary excretion was 19-30%. A lower proportion of radioactivity was found in the urine (13-25%) and excreted primarily as metabolites of hydrolysis or oxidation processes including: 4'-OH BP acid, BP acid, 4'-OH BP alcohol and dimethoxy BP alcohol, TFP acid, cis-OH-methyl TFP acid and trans-OH-methyl TFP acid (<0.01% of the administered dose was unchanged bifenthrin). Approximately half of the radioactivity excreted in the feces was as metabolites and included: hydroxymethyl-bifenthrin, 4'-OH-bifenthrin, 3'-OH-hydroxymethyl-bifenthrin, 4'-OH-hydroxy-methyl-bifenthrin, 3'and 4'-monomethyl-catechol-bifenthrin, dimethoxy-bifenthrin and 4'-methoxy-bifenthrin. Hydrolytic products related to mono- and dihydroxylated bifenthrin were also detected, which included 4'-OH-biphenyl alcohol, dimethoxy-biphenyl acid, dimethoxy-biphenyl alcohol, 4'-methoxy biphenyl alcohol and biphenyl alcohol, TFP acid, and cis and trans-hydroxymethyl-TFP acid.

Levels of radioactivity in plasma and whole blood were relatively low and elimination from plasma was faster than elimination from whole blood, decreasing to 1/6 of the peak concentration at days 78 and 99, respectively. Peak radioactivity levels in the blood occurred between 4 and 6 hours. Repeated dosing resulted in a 2-fold increase in peak blood radioactivity levels. Unchanged bifenthrin was detected in plasma along with major metabolites, biphenyl acid and biphenyl alcohol. The highest concentrations of radioactivity were found in fat and skin, in particular, the fat of females. Organs with higher fat concentrations had higher peak radioactivity concentrations and longer half-lives (for example: sciatic nerve and ovaries) while other organs had lower peak concentrations and shorter half-lives (for example, liver and kidney).

In vitro study results of radiolabeled bifenthrin in rat and mouse hepatic S9 microsomes indicated that metabolism was not extensive in the cells tested. The identified metabolites 4-OH bifenthrin and BP acid were formed by ring hydroxylation and scission of bifenthrin, respectively. Metabolic activity among species was male mouse > female mouse > male rat. In vitro treatment of rat and human hepatic microsomes indicated differences in P450 isoforms involved in bifenthrin metabolism, and rat microsomes also metabolized bifenthrin faster than human microsomes.

In acute toxicity studies, bifenthrin was highly toxic to rats and mice via the oral route, of low toxicity via the dermal route in rats and rabbits, and slightly toxic via the inhalation route in rats. Bifenthrin was non-irritating to the eyes and skin of rabbits, and was negative in a guinea pig sensitization test by the Buehler method. However, bifenthrin is considered a potential dermal sensitizer based on positive findings in a guinea pig Maximization test.

In the absence of acute toxicity testing with Capture 240 EC, acute toxicity studies with Capture 2EC, a similar end-use product also containing bifenthrin, were considered acceptable surrogates. On the basis of these data, Capture 240 EC is considered highly toxic to rats via the oral route, of low toxicity to rabbits via the dermal route, and of slight toxicity to rats via the inhalation route. It was minimally irritating to the eyes of rabbits, slightly irritating to rabbit skin, and a potential dermal sensitizer based on a lack of acceptable sensitization test.

Based on dietary (rat, mouse) or capsule (dog) repeat-dose studies conducted by the oral route, the most sensitive indicators of toxicity were signs of neurotoxicity (tremors, clonic convulsions, ataxia, abnormal gait, hypersensitivity to sound), which increased in frequency and intensity with increasing dose. In range-finding studies, mortality was observed at higher doses. In addition, effects on body weight, food consumption, organ weights, clinical chemistry, and haematology were also observed, but were not consistent in magnitude or direction of change among studies. Additional effects following repeat-dosing with bifenthrin included a delay of first estrous in the 1-year dog (capsule) study, retinal atrophy in rats from the chronic/oncogenicity study, increased incidence of submucosal lesions of the bladder at the highest dose tested, and bilateral germinal epithelial degeneration in testis in the mouse oncogenicity study at all dose levels tested. There was no indication that toxicity increased with increasing duration of exposure. No sex-related differences in sensitivity were noted, despite the greater deposition of bifenthrin in the adipose tissue of female rats in toxicokinetic studies, compared to males.

In a 21-day dermal toxicity study in rats, neurotoxicity, evident as paraesthesia, and skin irritation (desquamation, eschar, erythrema, ulceration, hyperplasia) were observed and increased in severity and incidence with dose.

Bifenthrin and several impurities were tested in a battery of in vitro and in vivo genotoxicity studies. Of the 17 studies using bifenthrin and nine studies using bifenthrin impurities, only the mouse lymphoma assay for bifenthrin yielded a positive result. On the basis of the overall findings, bifenthrin and the tested impurities are not considered genotoxic.

There was no evidence of treatment-related tumors in the dietary rat chronic/oncogenicity study. In the dietary mouse oncogenicity study, an increased incidence of lung and liver tumors was observed. In female mice, a statistically significant increase in the combined incidence of bronchioalveolar adenocarcinomas and adenomas was observed in the treated dose groups, compared to control. In comparison to historical controls, the tumor incidence in concurrent controls appeared low, likely contributing to the finding of statistical significance in the treatment groups. This study was considered to provide equivocal evidence for lung tumorigenicity as there was a lack of a dose response; the incidences were within the historical control range for the testing laboratory, the genotoxicity results were negative, and no treatment-related tumors were observed in rats. The overall weight of evidence suggested a low level of concern for the lung tumor findings in female mice. In high-dose male mice, a slight increase in the incidence of combined hepatocellular adenomas and adenocarcinomas was observed. Pre-neoplastic changes that are normally present in chemically-induced tumors were not observed. The incidence of tumors did not reach statistical significance in any treated group; however, a trend test was statistically significant for the incidences of hepatocellular adenocarcinomas and combined hepatocellular adenomas and carcinomas. The combined incidence in the high dose group exceeded the historical control incidence based on a single, relevant historical control reference study.

This study was considered to provide equivocal evidence for liver tumorigenicity, as there were no pre-neoplastic changes, the genotoxicity results were negative, and there was no similar response in female mice or in rats. The overall weight of evidence suggested a low level of concern for the liver tumor findings in male mice.

Bifenthrin did not affect reproductive indices in a two-generation dietary toxicity study in rats. Systemic effects in female parental animals included tremors, clonic convulsions, and decreased body weight and bodyweight gain. A minimal increase in stillbirths observed in the second generation pups believed to be caused by a heating failure in the animal room. As such, this finding was considered equivocal and of low concern. No effects were noted in offspring at the highest dose tested.

In rat dietary and oral gavage developmental toxicity studies, systemic toxicity in dams included tremors, clonic convulsions, splayed hindlimbs, hypersensitivity to sound, piloerection, twitching, and loss of muscle control. There was no evidence of developmental toxicity in the rat dietary study. A 10-fold lower dose in the gavage study produced a treatment-related increased incidence of a variation, hydroureter without hydronephrosis, at a dose that produced tremors in the dam. In an oral gavage rabbit developmental toxicity study, maternal animals showed evidence of neurotoxicity (tremors). No developmental toxicity was evident. Developmental and reproductive toxicity studies did not identify evidence of increased sensitivity of the young.

Several neurotoxicity studies, including gavage delayed neurotoxicity studies in hens and rats, as well as a gavage acute rat neurotoxicity study, a dietary 90-day rat neurotoxicity study, and a dietary rat developmental neurotoxicity (DNT) study, were available.

Bifenthrin did not cause delayed acute neurotoxicity in either the hen or the rat. In hens, oral (gavage) dosing with bifenthrin caused various neurotoxic effects (including unsteadiness, inability to walk/stand, wing-dropping, twitching of head/neck, jerking head movements, trembling), shortly after dosing. These effects reversed four to seven days after cessation of dosing. There were no neuropathology findings. In the rat tilting plane test, oral (gavage) dosing caused a slight increase in the mean angle of slip, stereotyped grooming and greasy appearance of fur, mortality, and decreased bodyweight.

In studies with rats, neurotoxic effects included tremors and twitching, reduced grip strength, increased arousal, increased landing foot splay, increased grooming, and clonic convulsions. In the acute gavage neurotoxicity study, neurotoxic effects occurred rapidly following dosing, with peak effects occurring in about 4-8 hours, and sooner at higher doses. In these studies, clinical signs of neurotoxicity were reversible following cessation of dosing. In the 90-day dietary neurotoxicity study, and in the maternal animals of the dietary DNT study, neurotoxic effects occurred from one week to several weeks after initiation of dosing, depending on dose level. Offspring in the DNT study exhibited increased grooming, reduced ambulatory and total motor activity, and increased acoustic startle at the dose causing maternal tremors and increased grooming. Neuropathology was not observed in toxicity studies except at the highest dose tested in the DNT study, where female offspring had a treatment related increased incidence of minimal axonal degeneration of the lumbar dorsal root fibres. Interpretation of this finding was complicated by the lack of examination of the low- and mid-dose groups; however, the incidence of this finding was outside historical control range. The results of the DNT study did not suggest increased sensitivity of the young relative to maternal animals.

In general, pyrethroid neurotoxicity is correlated with peak concentrations of the unchanged pyrethroid in blood, with bolus dosing resulting in larger internal doses and greater toxicity, compared to dietary administration. As the design of the DNT study does not consider the time of peak effect and may miss the window of peak toxicity for the pyrethroids, neurobehavioural assessments of the young in the DNT study may not be particularly informative. It is known that the metabolic clearance of pyrethroids in rats increases during maturation, primarily due to increased hepatic enzyme activity. Incomplete maturation of the enzyme systems in the liver which detoxify pyrethroids may result in increased pyrethroid concentrations in target tissues (for example: brain) and increased susceptibility of the young to toxicity, compared to adults receiving the same oral dose. Given the limitations of the DNT study in this regard, an adequate comparison of the sensitivity of the young animal is currently not available. A comparative oral gavage neurotoxicity study conducted in pups, weanling and adults, which considers the time of peak effect, could address this uncertainty. In the interim, this uncertainty has been reflected in the form of a database uncertainty factor.

Results of the toxicity studies conducted with bifenthrin, and its associated end-use product, are summarized in Appendix I, Tables 2 and 3. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 4.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents to the PMRA, including adverse effects to Canadian health or the environment. Bifenthrin and Capture 240 EC, which contains bifenthrin, were first registered for use in Canada on 23 May 2014. As of 3 May 2017, the PMRA received 1 human and 11 domestic animal incidents involving bifenthrin.

The human incident classified as major occurred in the United States and involved a child that accidentally ingested a small amount of a concentrated American termiticide product containing bifenthrin (7.9%). The child was hospitalized for several days and had symptoms of stomach pain, vomiting, lethargy, headache, hyperthermia, sweating, tingling skin, muscle tremors, unstable gait, nystagmus, and tachycardia. The incident was considered related to the reported pesticide exposure. Bifenthrin is only registered in one Canadian end-use product, Capture 240 EC. The label of the Canadian product indicates that it is a poison, to keep out of reach of children and that it must be stored locked. The label statements on the Canadian product address the circumstances of exposure reported in the United States incident. No additional mitigation measures are necessary.

The eleven domestic animal incident reports involving bifenthrin also occurred in the United States and were classified as animal death. In eight incidents, dogs were exposed as a result of coming in contact with an area treated with bifenthrin and other active ingredients, ingesting a bifenthrin product, or being treated directly with a bifenthrin product. Fish mortality as result of drift from an application site was reported in two incidents. Also, one incident involved a cat that was potentially exposed after an area inside the home was treated with a bifenthrin product. Although serious and fatal animal outcomes were described in American incidents, the reported exposure scenarios are rare and varied, and no Canadian domestic animal effects have been reported. No additional mitigation measures are necessary.

The incident report data was incorporated into the evaluation of bifenthrin.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account the completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the standard complement of required studies, including developmental toxicity studies in the rabbit and rat, and a reproductive toxicity study in the rat, were available. In addition, a developmental neurotoxicity study in the rat was available.

With respect to potential prenatal and postnatal toxicity, there was no indication of increased susceptibility of fetuses or young animals compared to parental animals in the rat reproductive study, in the rat dietary, rat gavage, and rabbit gavage developmental toxicity studies, or in the DNT study. In the 2-generation reproductive toxicity study, at a dose causing neurotoxicity (tremors, clonic convulsions) and bodyweight effects in dams, an equivocal increase in fetal stillbirths was observed while no effects were observed in offspring. In the rat gavage developmental toxicity study, an increased incidence of a variation, hydroureter without hydronephrosis, occurred at the same dose at which maternal toxicity (tremors) was observed. No developmental effects occurred in a gavage rabbit study at doses causing tremors, convulsions and lack of muscle control in the dams.

Young animals have incomplete maturation of the enzyme systems that detoxify pyrethroids and thus may be more susceptible due to higher and prolonged brain concentrations, compared to adults. Due to the lack of a comparative oral neurotoxicity study, an adequate assessment of sensitivity of the young is currently not available and residual uncertainty remains concerning susceptibility of the young to potential neurotoxic effects. This concern was reflected through the use of a 3-fold database uncertainty factor in the risk assessment. Since these concerns were addressed with a database uncertainty factor, the *Pest Control Products Act* factor was reduced to 1-fold.

3.2 Determination of Acute Reference Dose – all populations

To estimate acute dietary risk, the $BMDL_{20}$ of 2.6 mg/kg bw from an acute oral neurotoxicity study conducted with bifenthrin was selected, based on reduced motor activity in adult rats. Reduced motor activity was considered the critical endpoint since it is a sensitive neurobehavioral endpoint that is relevant to pyrethroid toxicity and is derived by a relevant route and duration of exposure. The $BMDL_{20}$ was specifically selected based on the reported variability of motor activity in control rats in the literature. The rabbit developmental toxicity study was considered a co-critical study for acute dietary risk. The NOAEL for the dams was 2.67 mg/kg bw/day based on neurotoxic signs (head and forelimb twitching) that were observed within two days of dosing at the LOAEL.

For the reasons outlined in the *Pest Control Products Act* Hazard Characterization Section, a 3-fold UF_{DB} was applied and the *Pest Control Products Act* factor reduced to 1-fold. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were also applied, resulting in a composite assessment factor (CAF) of 300.

The acute reference dose (ARfD) is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{2.6 \text{ mg/kg bw}}{300} = 0.009 \text{ mg/kg bw of bifenthrin}$$

3.3 Determination of Acceptable Daily Intake – all populations

To estimate risk from repeated dietary exposure, a NOAEL of 1.0 mg/kg bw/day was selected based on the results of the following co-critical toxicity studies: the oral NOAEL of 1.5 mg/kg bw/day in the 1-year dog study and the NOAEL of 1.0 mg/kg bw/day in the gavage developmental toxicity study in rats. In the rat developmental toxicity study, tremors were observed in the dams at the LOAEL of 2.0 mg/kg bw/day; a dose causing hydroureter without hydronephrosis in the fetuses. At the LOAEL of 3.0 mg/kg bw/day in the 1-year dog study, tremors and delayed first estrous were observed.

For the reasons outlined in the *Pest Control Products Act* Hazard Characterization Section, a 3-fold UF_{DB} was applied and the *Pest Control Products Act* factor reduced to 1-fold. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were also applied, resulting in a CAF of 300.

The acceptable daily intake (ADI) is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{1.0 \text{ mg/kg bw/day}}{300} = 0.003 \text{ mg/kg bw/day of bifenthrin}$$

The ADI provides a margin of 1200 to the NOAEL based on increased grooming counts, reduced motor activity, increased acoustic startle response, and neuropathology in female offspring at the LOAEL in the rat DNT study. Note that the neuropathology was observed in high dose female offspring, however, neither the low- or mid-dose groups were examined for neuropathology. Therefore, the margin was calculated to the low-dose group dose of 3.6 mg/kg bw/day. Additionally, the ADI provides a margin of >2500 to the LOAEL for bilateral germinal epithelial degeneration of the testes in male mice in the mouse oncogenicity study, to the dose showing an equivocal increase in lung tumors in female mice and to the equivocal liver tumors in male mice in the mouse oncogenicity study.

Cancer Assessment

As previously discussed, the lung and liver tumors noted in the mouse oncogenicity study were considered equivocal or not relevant to humans based on the weight of evidence. Overall, the endpoints selected for the non-cancer risk assessment are protective of these findings.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Occupational exposure to bifenthrin is characterized as short- to intermediate-term in duration and is predominantly by the dermal and inhalation route for mixers, loaders, and applicators and by the dermal route for post-application re-entry workers.

Short- and Intermediate-term Dermal

For short- and intermediate-term occupational exposures via the dermal route, a NOAEL of 50 mg/kg bw/day was selected from the 21-day dermal toxicity study in adult rats. At a dose of 100 mg/kg bw/day, staggered gait, exaggerated hind-limb flexion, and reduced tail flick latency were observed. This study is representative of the route of exposure, and was considered relevant for the short- and intermediate-term scenarios since there was no pronounced evidence of increased toxicity following increased duration of dosing in rats. The target Margin of Exposure (MOE) is 300. This includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability, and a 3-fold database uncertainty factor for concerns related to potential sensitivity of the young.

Since the endpoint selected in the dermal study was systemic neurotoxicity, it was considered protective of the tremors noted in dams in the developmental toxicity study, and the tremors and delayed estrous noted in the 1-year dog study.

Short- and Intermediate-term Inhalation

For short-, and intermediate-term occupational exposure via the inhalation route, a NOAEL of 1.0 mg/kg bw/day was selected from the gavage developmental toxicity study in rats. At a dose of 2.0 mg/kg bw/day maternal tremors were observed. No inhalation toxicity study was available, therefore, an oral endpoint was selected. The selection of this study was considered appropriate as it addresses the most sensitive toxic effect, neurotoxicity, and was considered relevant for the short- and intermediate-term scenarios, since there was no pronounced evidence of increased toxicity following increased duration of dosing in rats. In addition, worker populations could include pregnant or lactating women and, therefore, this endpoint is considered appropriate for the occupational risk assessment.

The target MOE is 300. This includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability, and a 3-fold database uncertainty factor for concerns related to potential sensitivity of the young.

3.4.1.1 Dermal Absorption

3.4.2 Occupational Exposure and Risk

3.4.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to bifenthrin during mixing, loading, application, clean up and repair. Dermal and inhalation exposure estimates for workers were generated from the PHED or AHETF databases and Agency default area treated per day values (ATPD).

Exposure to workers mixing, loading, applying, cleaning up and repairing equipment is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation route. Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted. Exposure estimates were derived for workers applying bifenthrin to raspberries using airblast equipment and handheld sprayers and in-furrow to potatoes using groundboom application equipment. The exposure estimates are based on mixers/loaders/ applicators wearing long sleeved shirt and long pants with gloves except for groundboom applicators for which non-gloved data was used.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

Exposure estimates were compared to the toxicological end points (no observed adverse effects levels) to obtain the MOE; the target MOE is 300 (Appendix I, Tables 5 and 6).

3.4.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with bifenthrin to complete tasks such as establishing irrigation lines, hand harvesting, scouting and tying/training. Given the nature of activities performed, dermal contact will be the primary route of exposure. Inhalation exposure is not expected to be of concern as bifenthrin is considered non-volatile with a vapour pressure of 2.4×10^{-5} Pa which is less than the NAFTA criteria for a non-volatile product for outdoor uses [1×10^{-4} kPa (7.5×10^{-4} mm Hg) at 20-30°C]. The duration of exposure is considered to be short- to intermediate-term.

Exposure to workers re-entering treated potato fields was not calculated as exposure to residues from in-furrow application at planting is expected to be negligible.

Dermal exposure to workers entering treated raspberry fields is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. Activity transfer coefficients are based on ARTF data. Chemical-specific dislodgeable foliar residue data were not submitted for raspberries. As such, a default dislodgeable foliar residue value of 25% of the application rate and a 10% dissipation per day were used in the exposure assessment.

Exposure estimates were compared to the toxicological end point to obtain the MOE; the target MOE is 300. Only exposure and risk to the activities with the highest TCs are presented as all activities exceed the target MOE of 300 (Appendix I, Table 7).

3.4.3 Residential Exposure and Risk Assessment

3.4.3.3 Bystander Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal. Application is limited to agricultural crops only when there is low risk of drift to areas of human habitation or activity such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.5 Food Residues Exposure Assessment

3.5.1 Exposure from Drinking Water

3.5.1.1 Concentrations in Drinking Water

Estimated environmental concentrations (EECs) of bifenthrin in potential drinking water sources (groundwater and surface water) were generated using computer simulation models. EECs of bifenthrin in groundwater were calculated using the PRZM-GW model to simulate leaching through a layered soil profile over a 50-year period. The concentrations calculated using PRZM-GW are based on the flux, or movement, of pesticide into shallow groundwater with time. EECs of bifenthrin in surface water were calculated using the PRZM/EXAMS models, which simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Pesticide concentrations in surface water were estimated in a small reservoir.

A Level 1 drinking water assessment was conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. Appendix I, Table 8 lists the application information and main environmental fate characteristics used in the simulations. Fifteen initial application dates between February and September were modelled. The model was run for 50 years for all scenarios. The largest EECs of all selected runs are reported in Appendix I, Table 9. In this case, both the modelled EECs and the limit of solubility are reported. For groundwater modelling, the potato rate was modelled. Higher leaching potential would be expected from an in-furrow application at 337 g a.i./ha compared to the foliar method of application for raspberries at a lower rate (2 × 112 g a.i./ha). For surface water modelling, comparative modelling (with in-furrow and t-band applications relevant to the use pattern for potato in-furrow, and foliar applications for raspberries) indicated lower EECs from the potato rate compared to the raspberry rate. Although the potato rate is higher, the application method for potato includes application of the pesticide below the soil surface, which reduces the availability of the pesticide for runoff. Therefore, the more conservative EEC values are reported for raspberries. Details of water modelling inputs and calculations are available upon request.

3.5.2 Residues in Plant and Animal Foodstuffs

The residue definition for risk assessment and enforcement in plant products and animal commodities is bifenthrin. The data gathering/enforcement analytical methods are valid for the quantitation of bifenthrin residues in crop and livestock matrices. The residues of bifenthrin are stable in representative matrices from five crop categories (high water, high oil, high protein, high starch and high acid content) and processed commodities for 6-49 months when stored at -38 to 0°C. Therefore, bifenthrin residues are considered stable in all frozen crop matrices and processed crop fractions for the duration of storage. The raw agricultural commodities (potato; soybean; tomato; pear) were processed and bifenthrin residues only concentrated in the following processed commodities: soybean aspirated grain fractions (AGF) (83-fold); pear wet pomace (peeled) (2.8-fold) and pear wet pomace (ground) (14.6-fold). Adequate feeding studies were carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Crop field trials conducted throughout the United States and India (tea only) using end-use products containing bifenthrin at approved or exaggerated rates in or on the various petitioned commodities are sufficient to support the proposed maximum residue limits (MRLs).

3.5.3 Dietary Risk Assessment

Acute and chronic (cancer and non-cancer) dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.16), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.5.3.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the refined chronic cancer and non-cancer analysis for bifenthrin: projected percent crop treated data for potato and raspberry; American percent crop treated data for crops grown in the United States (where available); default and experimental processing factors (where available), residues of bifenthrin in or on carrot; potato; head lettuce; spinach; mustard greens; broccoli; cauliflower; cabbage; soybean; edible-podded pea and bean; succulent shelled pea and bean; tomato; pepper (bell and nonbell); eggplant; cantaloupe; cucumber; summer squash; pear; mayhaw; raspberry; blackberry; celery and tea based on supervised trial median residue (STMdR) values and anticipated residues for all animal commodities. The refined chronic dietary exposure from all supported bifenthrin food uses (alone) for the total population, including infants and children, and all representative population subgroups is less than 16.5% of the ADI. Aggregate exposure from food and drinking water is considered acceptable. The PMRA estimates that chronic dietary exposure to bifenthrin from food and drinking water is 16.7% (0.000500 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for children 1-2 years old at 33.9% (0.001017 mg/kg bw/day) of the ADI.

3.5.3.2 Acute Dietary Exposure Results and Characterization

The following assumptions were applied in the refined acute analysis for bifenthrin: United States monitoring data (where available); default and experimental processing factors (where available), residues of bifenthrin in or on carrot; potato; head lettuce; spinach; mustard greens; broccoli; cauliflower; cabbage; soybean; edible-podded pea and bean; succulent shelled pea and bean; tomato; pepper (bell and nonbell); eggplant; cantaloupe; cucumber; summer squash; pear; mayhaw; raspberry; blackberry; celery and tea based on maximum values and anticipated residues for all animal commodities. The refined acute dietary exposure (food alone) for all supported bifenthrin registered commodities is estimated to be 33.8% (0.003045 mg/kg bw/day) of the ARfD for the general population (95th percentile, deterministic). Aggregate exposure from food and drinking water is considered acceptable: 35.4% of the ARfD for the general population.

3.5.4 Aggregate Exposure and Risk

3.5.5 Maximum Residue Limits

For the MRLs for this active ingredient, please refer to the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage in the Pesticides and Pest Management section of Health Canada's website.

The nature of the residues in animal and plant matrices, analytical methodologies, field trial data, and acute and chronic dietary risk estimates are summarized in Appendix I, Tables 1, 10 and 11.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The PMRA requested additional Section 12 data during the conditional registration period which included the following:

- Aerobic soil and water/sediment studies examining the transformation of the isomers for bifenthrin, 4'-OH bifenthrin and TFP acid – as requested by the European Commission,
- A biomonitoring program to assess whether risks to organisms remain low under conditions of use under Canadian conditions,
- A study which determines the residual toxicity for non-target arthropods and the potential for re-colonisation,
- Tissue residue-based acute and chronic fish ecotoxicity studies,
- Additional biomagnification and bioconcentration studies for fish and aquatic invertebrates, and
- Terrestrial field dissipation study conducted in an ecoregion equivalent to Canada use sites.

In addition, the bioaccumulation assessment was updated using the most recent OECD guidelines and recommended calculation methods.

Based on submitted information, bifenthrin is classified as practically insoluble in water. The vapour pressure and Henry's law constant suggest that bifenthrin has low potential to volatilize from water and moist soil. An atmospheric model predicted an atmospheric half-life of less than one day. However, there is a high amount of uncertainty around this estimate as a high fraction of bifenthrin is expected to sorb to airborne particles which will decrease the availability of bifenthrin to be degraded by atmospheric oxidation.

Technical bifenthrin primarily consists of the cis-isomer with trace amounts of the trans-isomer. When bifenthrin treated soil or water was irradiated, it underwent isomerization and formed a higher ratio of trans-bifenthrin. The enantiomer ratios of two stereoisomers of cis-bifenthrin (R-*cis*-bifenthrin and S-*cis*-bifenthrin), 4'-OH bifenthrin and TFP acid remained relatively the same under laboratory aerobic conditions in absence of light. Therefore, the enantiometric ratios of the R- and S-*cis*-bifenthrin, 4'-OH bifenthrin and TFP acid are not expected to change significantly in the aerobic environment over time. Slight preferential enantiometric transformation between the R-*cis*-bifenthrin and S-*cis*-bifenthrin was observed under laboratory anaerobic soil conditions; however, it is not expected to impact the ratio of these enantiomers significantly in the natural environment as all enantiomers of bifenthrin are very persistent under anaerobic condition.

Bifenthrin has a high soil adsorption coefficient (K_d = 26,013 – 154,299), is highly absorptive to soil and exhibits very limited mobility. Bifenthrin is moderately persistent to persistent in aerobic soils with DT_{50} values ranging from 78.7 to 203 days and persistent in anaerobic (flooded) soils with DT_{50} values greater than 1000 days under laboratory conditions. The primary dissipation route of bifenthrin in terrestrial ecosystems is biotransformation; however, the rate varies depending on the climate and soil characteristics. The results of terrestrial field studies conducted in Canadian equivalent ecoregions confirm the laboratory findings. Under field conditions, bifenthrin was moderately persistent to persistent with DT_{50} values ranging from 80 to 215 days with 11-27% of residues carried over to the next growing season. Bifenthrin was mainly detected in the 0-30 cm soil layer without any evidence of movement below 30 cm soil depth in field studies conducted in United States, Germany, Italy and France. Bifenthrin is not expected to leach to ground water.

No major transformation products were detected in the terrestrial laboratory and field studies. The minor transformation products identified were 4'-OH bifenthrin, TFP acid, biphenyl acid, biphenyl alcohol and biphenyl aldehyde. The mobility of TFP acid and 4'-OH bifenthrin was tested in a variety of soils. TFP acid is classified as either moderately mobile or very highly mobile depending on soil. The mobility of TFP acid is strongly dependent on the pH and the organic carbon content of the soil. It is less mobile in soils with low pH and high organic carbon content. 4'-OH bifenthrin is less mobile than TFP acid and is classified as either low or immobile depending on the soils. The transformation products are not expected to form in appreciable amount in the natural environment and are unlikely to leach to ground water in a significant amount on a seasonal basis.

Bifenthrin can enter the aquatic environment through spray drift and runoff from the application site. Bifenthrin is highly insoluble in water and hydrolysis is not an important route of transformation. Photolysis and biotransformation can be important processes of degradation.

In the laboratory photolysis study, bifenthrin underwent isomerization from cis-bifenthrin to trans-bifenthrin and transformed to bifenthrin alcohol and TFP acid that reached maximums of 19% and 10.2% of applied, respectively. In aerobic water-sediment biotransformation studies, bifenthrin partitioned from the water into sediment after a few days and remained moderately persistent to persistent with whole system DT_{50}'s ranging from 92.9 days to 276 days. 4'OH-bifenthrin was the only major transformation product detected in the sediment of the aerobic water/sediment system. Minor transformation products detected were TFP acid, biphenyl acid and biphenyl alcohol. These minor transformation products are not expected to be formed in high quantities in the environment. Under anaerobic conditions, bifenthrin is expected to be persistent based on the results from the flooded soil study (DT_{50}>1000 days).

Under aquatic field conditions, bifenthrin is expected to quickly partition from the water to the sediment. Microbial biotransformation is expected to be the most important route of transformation in aquatic systems. In an aquatic field study conducted in Alabama, bifenthrin was much more persistent than predicted by the laboratory studies. The estimated DT_{50} of bifenthrin residues in pond water of the aquatic field study was 609 days. Bifenthrin residues in the pond sediment declined slowly until study termination, two years after the last application. Although half-lives could not be estimated, the mean concentration in sediment samples collected 737 days after the final application were approximately 21% of the highest mean observed on day 57 after the last treatment. This was possibly due to its persistence in soil and the continuous input into the pond from runoff for the two years following the last application.

The majority of the environmental fate endpoints from the open literature, while highly variable, confirm the persistence and immobility characteristics of bifenthrin. Some reported half-lives were less than one year and were comparable to those obtained from the submitted environmental fate studies. A few reported half-lives were greater than one year and were significantly greater than those obtained from the submitted studies.

A review of the published literature indicated the presence of bifenthrin in freshwater sediment, urban estuarine sediment, irrigation and storm runoff in the United States. While the available data from the United States Geological Survey's National Water-Quality Assessment Program, the United States Environmental Protection Agency's (UESPA) Storage and Retrieval Data Warehouse, and the California Department of Pesticide Regulation reported the low frequency of bifenthrin detections, several recent articles reported bifenthrin to be one of the most frequently detected pyrethroids in water samples collected from runoff and urban or agricultural creeks. Bifenthrin is also a common contaminant in sediment samples at concentrations up to 430 µg/kg sediment.

Based on a log K_{ow} greater than six, bifenthrin has a high potential to bioaccumulate in aquatic organisms. At the time of original registration, the PMRA determined that the measured bioconcentration and bioaccumulation factors were highly variable and were both above and below bioaccumulation cut-off values for TSMP. A review of bioaccumulation of bifenthrin in both the terrestrial and aquatic environment reported in the European Commission's Additional Report by France (2010) which included a fish dietary biomagnification study, field data and modelling information, indicated that bifenthrin is found in each level of the food chain, but biomagnification in upper trophic organisms was not observed. It also found that despite the availability of several studies, the bioaccumulation of bifenthrin is not fully characterised as the phenomenon appears to depend on species, life stage and exposure. PMRA requested studies reported in foreign reviews that were not originally submitted to the PMRA for review. PMRA reviewed these studies and integrated this information into the assessment. When all relevant information was integrated together, the weight of evidence indicated that the TSMP criteria were indeed met. In particular, it was concluded that the field bioaccumulation factor (BAF) values were a better indicator of bioaccumulation than the single dietary laboratory study conducted on one species. The BAFs from the field study considered multiple species and pathways of exposure under environmentally relevant conditions.

Calculations for bioconcentration and bioaccumulation factors were updated using the most recent OECD recommended calculation methods correcting for lipid content and growth. Results of the laboratory bioaccumulation studies showed that bifenthrin bioconcentrates significantly in some species. Bioconcentration factor (BCF) values in carp (*Cyprinus carpio*) (kinetic BCF corrected for growth rate and lipid content: 1265 – 1861) are low compared to those for bluegill sunfish (kinetic BCF: 3400-12850) and adult fathead minnow (*Pimephales promelas*) (steady state BCF: 21000-30000). The kinetic BCF for *Daphnia magna* corrected for growth rate is 6273. Bifenthrin did not biomagnify in bluegill sunfish, the biomagnification factor (BMF) was <1.0; however, assimilation efficiency (α) of bifenthrin in bluegill sunfish was very low (3.9% to 5.8%). In comparison, PCBs that are known to have BMFs of >1 have an α of 40-60%. Low assimilation efficiency can be a result of some limitation to the uptake via the gut due to steric effects or bound residues that cannot partition off the food or a combination of these factors. Under field conditions which consider all exposure pathways, estimated bioaccumulation factors (BAFs) indicate significant bioaccumulation. Results of the aquatic field study conducted in Alabama suggested that BAFs >5000 were sustained in several fish species longer than 150 days after the last application. Although there are uncertainties and variability (spatial and temporal) associated with field studies, the field BAF values are considered to offer a reasonable characterization of the exposure history of fish to bifenthrin and were found to be consistent with BCF values obtained under controlled laboratory conditions.

A field monitoring study of dolphins from the Brazilian coast detected bifenthrin residues in liver, breast milk and placental samples (Alonsa, et al. 2012). The results of this study provide evidence of exposure and accumulation of bifenthrin in marine mammals and maternal transfer by both gestational and lactation pathways in non-agricultural areas far from the source of release. Marine mammals are at the top of the marine food chain. Occurance of bifenthrin in their liver samples provides further evidence of bioaccumulation of persistent chemicals in upper trophic level of food chain.

The requested biomonitoring program under Canadian conditions of use was not submitted. A biomonitoring study provided additional residue information on bifenthrin in earthworms and terrestrial small mammals and aquatic biota in a treated field and adjacent ponds at two different locations in Germany at three different time periods. The treatment rate of these studies was 1/10th of the Canadian rate (Canadian rate: 112 g a.i./ha). The results of these European studies are considered to be of limited value in terms of assessing bioaccumulation in aquatic biota because in most cases, residues in water and sediment were undetectable, very close to or below the limit of quantitation (LOQ) and could not confirm exposure which precluded calculating a bioaccumulation ratio under field conditions. The lack of detections in aquatic environment under the European conditions cannot be interpreted as a lack of exposure under Canadian use conditions. Bifenthrin residues were detected in the earthworm and small rodent samples collected from treated fields. Bifenthrin residues in earthworms were highly variable. In general, the shallow burrowing earthworm had lower mean bifenthrin residues than *L. terrestris*, deep burrowing earthworms. The mean bifenthrin residue in *L. terrestris* peaked at 0.32 mg a.i./kg between 7 to 21 days before declining and remained detectable 119 days after the last application. Bifenthrin residues in small mammal samples were low and highly variable. The majority of samples were under the level of detection or quantification. The highest mean bifenthrin residue in small mammals was 0.0142 mg a.i./kg from Day 6 after the last treatment in Autumn 2014. Specimens containing detectable bifenthrin residues were captured in the treated field but not from the edge of the field and surrounding area. The bifenthrin residues were lower in the small mammal gut samples and gut contents than in the small mammal samples without gut or gut content. This indicated that small mammals had assimilated and accumulated bifenthrin and retained the residues in the body.

A summary of environmental fate data is presented in Appendix I, Tables 12, 13, and 14.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models that take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e., protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

There are many published articles examining the toxicity of bifenthrin to pollinators, non-target arthropods and aquatic organisms. The results of up-to-date published journal articles confirm the overall conclusion of bifenthrin's toxicity to pollinators, non-target arthropods and aquatic organisms. The reported endpoints in the open literature do not change the outcome of the risk assessment; therefore, the risk assessment is primarily based on the submitted data.

4.2.1 Risks to Terrestrial Organisms

A risk assessment of bifenthrin to terrestrial organisms was based upon evaluation of toxicity data for earthworms (acute and chronic exposure), bees (acute oral and contact exposure and field aged residue), non-target beneficial arthropods (acute contact laboratory studies, aged residue and extended laboratory study), birds (acute oral, dietary and reproduction), mammals (acute oral and reproduction) and terrestrial plants (effects on seedling emergence).

A summary of terrestrial toxicity data for bifenthrin, formulated products and its transformation products is presented in Appendix I, Table 15. Terrestrial toxicity data for Talstar 8 SC, an end-use product containing nominal 80 g a.i./L, were used as surrogate data when toxicity data for bifenthrin or Capture 240 EC were not available. The screening and refined risk assessment for terrestrial organisms other than birds and mammals are presented in Appendix I, Tables 16 and Table 17, respectively.

No major transformation product was identified or detected in the terrestrial field dissipation studies or laboratory soil studies. Therefore, bifenthrin is expected to be the only residue of concern in the terrestrial habitat.

Earthworms: The screening level risk assessment of bifenthrin indicates that the LOC for earthworms was not exceeded for either acute or chronic exposure. As the LOC was not exceeded for bifenthrin, RQ was not calculated for its transformation product, 4'OH-bifenthrin, which is less toxic and has a lower EEC than bifenthrin.

Bees (pollinators): Pollinators can be exposed to bifenthrin from contact and/or feeding on contaminated parts of plants, for example, pollen and nectar. In-hive bees, including immature bees, can be exposed via contaminated plant materials brought back by foraging bees. The screening level risk assessment of bifenthrin concluded that the LOC for bees was exceeded (RQ = 2.1 for acute oral and 99 for acute contact). According to the results of a field-aged residue study, residues on plants after a foliar spray could remain at toxic levels for several days. Potential exposure and risk to bees will be further mitigated through label statements which prohibit application during the crop blooming period and require off-field drift to be minimized.

Beneficial arthropods: The toxicity of bifenthrin was determined for five different beneficial arthropod species: ladybird beetle (*Coccinella septempunctata* L.), parasitic wasps (*Aphidius rhopalosiphi*), ground beetles (*Poecilus cupreus* L.), green lacewing (*Chrysoperia carnea* Steph.) and predatory mites (*Typhlodromus pyri*). The risk to non-target arthropods was assessed using maximum cumulative in-field and off-field EECs on plant surfaces, calculated from a direct spray on a field. The acute contact test exposing adult *A. rhopalosiphi* to glass plates or maize leaves treated with 7.5 g a.i./ha of Talstar 8 SC had 100% mortality. Therefore, the screening level RQs from in-field and off-field exposures to bifenthrin exceeded the LOC for uses on raspberry as the treatment rate was significantly lower than the single application rate for raspberry. The results of extended laboratory tests on natural substrate were used for all five species for screening risk assessment purposes. The in-field RQs were 1500, 15, 25 and 1115 for *C. septempunctata* L. (ladybird beetle), *A. rhopalosiphi* (aphid parasitoid), *C. carnea* (green lacewing) and *T. pyri* (predatory mite), respectively. The corresponding off-field RQs were 885, 9, 14 and 658, respectively. The RQs of these four species exceeded the LOC. The RQ for *P. cupreus* L was 0.84 and did not exceed the LOC.

The bifenthrin EEC values for beneficial predatory and parasitic arthropods were refined to consider foliar interception. The exposure estimates are assuming deposition to a 2-dimensional structure. Therefore, the values can be corrected to take into account the 3-dimensional structure where a certain fraction is intercepted by the crop (for in-field exposure) or the off-field vegetation (for off-field exposure). For the in-field EEC, crop-specific foliar interception factors are applied to the application rate. No factors are proposed for raspberries. As raspberry plants at fruiting stage have similar foliage coverage as vines during flowing and fruiting stage, the deposition fractions for vines (Fint = 0.8 and Fsoil = 0.2) are used as surrogates. For the off-field EEC, a vegetation distribution factor of 0.1 is applied to the application drift rate.

The refined in-field RQs were 1202, 12, 20 and 894 for *C. septempunctat* L., *A. rhopalosiphi*, *C. carnea* and *T. pyri*, respectively, and still exceeded the LOC. The refined off-field RQs determined based on the uses on raspberries were 88.5, 1.4 and 7.43 for *C. septempunctat L.*, *C. carnea* and *T. pyri*, respectively and exceeded the LOC. As the use of bifenthrin on raspberries is expected to pose potential risks to non-target arthropods including those used in Integrated Pest Management, precautionary statements and directions to minimize off-field drift are required on the label.

Terrestrial plants: The toxicity of Talstar 8 SC to six non-target terrestrial plant species was determined through a seedling emergence test. No treatment-related adverse effects (i.e., >25% effect) were observed in any plant species up to 0.08 mg a.i./kg dw soil, which was the highest test concentration. Therefore, the NOEC and EC_{25} were 0.08 mg a.i./kg dw soil and > 0.08 mg a.i./kg dw soil, respectively. The soil EEC values based on the highest application rates for potato and raspberries were 0.150 mg a.i./kg dw soil and 0.094 mg a.i./kg dw soil, respectively. The RQ values based on the no-effect endpoints for use on potato and raspberries were <1.9 and <1.2, respectively. Further testing was not completed to determine the level at which effects would be observed as such the true no-effects level may be higher than 0.08 mg ai/kg dw soil. Bifenthrin is a pyrethroid insecticide and the mode of action is not expected to pose adverse effect on plants. Therefore, the use of bifenthrin is not expected to pose a risk to terrestrial plants and mitigation measures are not required.

Terrestrial vertebrates: Birds and mammals may be exposed to bifenthrin following the ingestion of plant materials and insects sprayed with bifenthrin during foliar application. The screening level risk assessment for Capture 240 EC is conducted for direct on-field exposure, assuming exposure occurs entirely through the consumption of food sources contaminated with bifenthrin at the maximum nomogram residue levels, the most conservative scenario. Concentrations of bifenthrin on different food guilds are calculated based on the highest rate for foliar application (i.e., 2 × 112 g a.i./ha) with a 30-day interval and a foliar half-life of 10 days.

Birds: Bifenthrin is slightly toxic to Northern bobwhite (*Colinus virginianus*) and is practically non-toxic to mallard duck (*Anas platyrhynchos*). Reproduction studies did not detect any effects or dose response relationship in any measured reproductive parameter, including number of eggs laid, egg weights, egg shell thickness, number of infertile eggs, early and late embryonic death, hatching, chick health, chick body weight and number of 14-day survivors, up to the highest treatment level of 75 mg a.i./kg dw diet. The risk quotients ($RQs<1$) for acute and reproductive exposure to birds at the screening level risk assessment do not exceed the LOC for small, medium or large birds (Appendix I, Table7). Therefore, the use of bifenthrin on raspberries is not expected to pose a risk to birds.

Mammals: The laboratory toxicity of bifenthrin to mice and rats was used to assess risk to small terrestrial mammals. The results of the acute toxicity test suggest that bifenthrin is highly toxic to mice and is not gender specific (Appendix I, Table 15). In the rat reproduction study, reduced body weight gain in parent and offspring and increased litter incidence of stillborn pups were observed. The risk assessment for mammals are conducted using these two endpoints (acute LD_{50}: 43 mg a.i./kg bw/day and NOAEL for reproduction: 3 mg a.i./kg bw/day) and are presented in Appendix I, Table 18 and Table 19, respectively.

The screening RQs for acute exposures to medium- and large-sized mammals exceeded the LOC but not for small-sized mammals. The screening RQs for reproductive exposures to all three sizes of mammals exceeded the LOC. Therefore, further mammalian risk characterization was conducted. To further characterize the risk, the assessment was expanded to all relevant food guilds, with concentrations of bifenthrin on food items to cover both maximum and mean residue values from the nomogram. Both in- and off-field exposure estimates are considered in this assessment. When considering the maximum residues, the acute on-field RQs (1.32-2.66) exceeded the LOC for medium herbivores and large herbivores, except large herbivores in the long grass food guild. The acute off-field RQs exceeded the LOC for medium herbivores feeding on short grass and forage crops. The reproductive risk from on-field exposure exceeded the LOC for small insectivores, medium herbivores and large herbivores. The reproductive risk from off-field exposure exceeded the LOC for medium and large herbivores, except large herbivores feeding on long grass. When considering the mean residues, only the on-field RQs for medium sized herbivorous mammals feeding on short grass and forage crops exceeded the LOC slightly. The reproductive risk from off-field exposure did not exceed the LOC for any size of mammals. Although the LOC was exceeded for medium sized mammals for on-field exposures, the identified risk is a result of mammals feeding solely on contaminated food, a scenario that would not normally occur. Consequently, the on-field risk to mammals is unlikely to be realized.

As bifenthrin is highly toxic to mammals, a statement informing users of this is required on the label for the end-use product, Capture 240 EC.

4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data for bifenthrin, its formulated products and transformation products is presented in Appendix I, Table 20.

4.2.2.1 Screening Level Assessment

To assess the potential for adverse effects, conservative screening level EECs in the aquatic environment based on a direct application to water were used as the exposure estimates. A risk assessment of bifenthrin was undertaken for freshwater and marine aquatic organisms based on available toxicity data to invertebrates (acute and chronic), fish (acute and chronic), amphibians (using fish as surrogate data), and algae (acute). Aquatic toxicity data for other formulations were used as surrogate data when data for neither bifenthrin nor Capture 240 EC were submitted.

For acute toxicity studies, uncertainty factors of 1/2 and 1/10 the EC_{50} (LC_{50}) are typically used in modifying the toxicity values for aquatic plants and invertebrates, and fish species, respectively when calculating RQs. No uncertainty factors were applied to chronic NOEC endpoints. The calculated RQs for bifenthrin are summarized in Appendix I, Table 21 (screening level). A risk assessment for 4'OH-bifenthrin was not conducted for the following reasons: it was less toxic than bifenthrin for the species tested and it was not expected to form at concentrations higher than bifenthrin.

Species sensitivity distribution (SSD) analysis was conducted when sufficient acute toxicity data were available to determine hazardous concentration to five percent of species (HC_5) using the software program ETX 2.1. The HC_5 is the concentration which is theoretically protective for 95% of species. At the HC_5 exposure level, five percent of all species may be exposed to a concentration which exceeds the toxicity value. The variability around the fraction of species affected (FA value) is indicated by the lower and upper confidence limits (90% CI), which indicates the minimum and maximum percent of species that may be affected at the HC_5 value.

Freshwater invertebrates: Bifenthrin is toxic to aquatic invertebrates such as *Daphnia magna* and *Chironomus riparius*. Talstar 80g/L Flowable was less acutely toxic to *D. magna* than the bifenthrin technical, but is still toxic to freshwater invertebrates. 4'-OH bifenthrin was much less acutely toxic than the parent to *C. riparius*. A total of 10 acute toxicity endpoints for freshwater invertebrate species compiled from open literature search and applicant data are available for SSD analysis. The median HC_5 value for bifenthrin for acute effects on freshwater invertebrates was determined to be 0.009 µg a.i./L (90% CI: 0.0006 to 0.044 µg a.i./L). The fraction of species affected (expressed as a percentage of all species) at the HC_5 value ranges from 0.61 to 20.1% (90% CI).

Chronic exposure to bifenthrin resulted in reduced reproduction and growth of adult daphnids and declined emergence rate of the fresh water midge *C. riparius*. As the aquatic risk assessment is mainly based on EECs in surface water, the *C. riparius* toxicity endpoint determined from the water-spiked toxicity test was used for the chronic aquatic invertebrate risk assessment.

The screening level RQs for acute and chronic exposure of freshwater invertebrate to bifenthrin exceeded the LOC. Therefore, further refinement of the aquatic risk assessment was required.

Freshwater fish: Bifenthrin is very highly toxic to rainbow trout, bluegill sunfish, fathead minnow, medaka, common carp, and zebra fish. A total of six acute toxicity endpoints for freshwater fish species based on submitted studies were available for SSD analysis. The median HC_5 value of bifenthrin for acute effects on freshwater fish was determined to be 0.008 µg a.i./L (90% CI: 0.009 to 0.02 µg a.i./L). The fraction of species affected (expressed as a percentage of all species) at the HC_5 value ranges from 0.25 to 27.7% (90% CI).

For the chronic assessment on fish, fry survival was the most sensitive endpoint for the full life cycle test conducted with fathead minnow.

The screening level RQs for acute and chronic exposure of freshwater fish to bifenthrin exceeded the LOC. Therefore, further refinement of the aquatic risk assessment was required

Freshwater amphibians: In absence of any actual amphibian data, acute freshwater fish HC_5 and fathead minnow full life cycle NOEC were used as surrogates for acute and chronic amphibian endpoints, respectively. The risk for amphibians was characterized at the screening level by comparing EECs in 15 cm water depth with fish toxicity endpoints as surrogates for aquatic life-stages of amphibians. The screening level RQs exceeded the LOC.

Freshwater algae: A 72-hour limit test conducted with green alga *Desmodesmus subspicatus* reported that bifenthrin did not exert any toxic effect on *D. subspicatus* at 6.3 mg a.i./L. The screening level RQ did not exceed the LOC.

Marine/estuarine species: In laboratory studies, bifenthrin was acutely toxic to mysid shrimp (*Mysidopsis bahia*), eastern oyster (*Crassostrea virginica*) and sheepshead minnow (*Cyprinodon variegatus*). Chronic exposure to bifenthrin for 28 days resulted in reduced survival, growth and reproduction of mysid shrimp. The screening RQs exceeded the LOC for mysid shrimp and sheepshead minnows; therefore a more refined assessment is needed.

The endpoints for acute embryo survival and acute shell deposition of eastern oyster differed by two orders of magnitude. Therefore, the screening RQ for acute shell deposition exceeded the LOC while the screening RQ for acute embryo did not. As the EC_{50} for acute shell deposition endpoint was greater than the highest treatment level, the screening RQ may be overestimated.

4.2.2.2 Refined Risk Assessment

Aquatic field studies

Higher tier studies confirm that the most sensitive aquatic organisms are invertebrates. Mesocosm systems show that exposure to bifenthrin decreases species diversity and abundance of the invertebrate community – pelagic zooplankton and benthic invertebrate populations (for example, calanoids, chironomid, oligochaeta, chaoboridae), at environmentally relevant concentrations. Phytoplankton and macrophyte communities showed no direct effects from bifenthrin exposure; in some cases transient effects (increase or decrease in adundance of phytoplankton) were observed, however, these effects were not considered to be treatment related. The NOEC values based on decreased abundance of zooplankton and macroinvertebrate communities were 0.001 µg a.i./L and 0.005 µg a.i./L, respectively. Although effects were observed to the zooplankton and macroinvertebrate communities at concentrations as low as 0.005 and 0.015 ug/L (LOEC), the taxonomic diversity of the community remained unchanged at 0.015 ug a.i./L. In addition, the invertebrate populations adversely affected at the 0.015 ug a.i/L treatment concentration level were shown to recover within seven days (i.e., rotatoria and some crustacea – for example, copepods) and 14 days (i.e., chaoboridae). Based on the short recovery period observed, consideration of the NOEC of 0.015 ug a.i./L (taxonomic richness) for the risk assessment would be expected to be sufficiently protective of aquatic ecosystems.

Similar effects to the aquatic invertebrate community were observed in the Alabama aquatic field study. In this study, biomonitoring was conducted in a pond for up to two years after bifenthrin was applied aerially to adjacent cotton fields. There were clear effects on various biota in the pond due to bifenthrin treatments:

1. Immediate and prolonged elimination (for at least one year after treatment) of calanoid copepods.
2. Immediate and prolonged extremely low abundance (for at least one year after treatment) of the mayfly, *Caenis* sp.
3. Disappearance of the damselfly *Enallagma* after treatment for at least one year
4. Severe reduction of chironomid populations.
5. Reduction in survival and reproductive potential of *Daphnia* and snails.

Effects observed in this pond study were shown to persist for a longer period of time than was observed in the mesocosm study. The major limiting factor of the pond is the lack of multiple exposure concentrations where an NOEC (community, abundance etc.) could be determined. Although the pond study clearly shows immediate and prolonged effects to specific aquatic species, it is not amenable for quantitative use in the risk assessment because an NOAEC cannot be determined.

The multiple dose design of the mesocosm study does allow for determination of an NOAEC endpoint for quantitative use in the risk assessment; however, a number of deficiencies and uncertainties limit its accuracy, therefore a safety factor is required to ensure it is protective. These deficiencies are:

- The exposure concentrations used over the test period are uncertain. Four of the seven nominal test concentrations were below the analytical detection limit. In addition, measured concentrations of bifenthrin in water decreased to below the limit of quantitation between days 3 and 7 after treatment in all treatments. Therefore, the reported NOEC, based on nominal test concentrations, likely represents an underestimate of the true NOEC.
- Effects observed in the multi-year field pond study were observed at lower measured concentrations than those observed in the mesocosm study based on nominal test concentrations. The NOEC from the mesocosm study is based on the nominal test concentration instead of the measured concentration. Therefore, the NOEC likely represents an underestimate of effects.

Based on the deficiencies above, the PMRA has determined that a safety factor of three be applied to the NOEC of 0.015 µg a.i./L so that the significance of these uncertainties is reduced and the chosen NOEC is protective of the community structure and individual aquatic organisms. Note that this safety factor was also used by the European Food Safety Authority (EFSA).

Spray drift and runoff refinements

Given the conservative assumption made in the screening level assessment (i.e., direct over spray to a water body), refined assessments were conducted to better characterize the risk to aquatic organisms. For groups where the screening LOC is exceeded (i.e., RQ ≥1), a refined assessment was conducted to determine if the risks are acceptable from spray drift and runoff separately. In addition to spray drift and runoff refinement, the results of higher tier studies such mesocosm and field studies were considered and compared in refined risk assessment.

Spray drift refinement: The risk to aquatic organisms was further characterized by taking into consideration the concentrations of bifenthrin that could be deposited in off-field aquatic habitats that are downwind and directly adjacent to the treated field through spray drift. The maximum amount of spray that is expected to drift one metre downwind from the application site during spraying using late growth stage airblast application is 59% of the application rate. The estimated EEC values were 16 µg a.i./L and 85 µg a.i./L for permanent water bodies (80 cm deep) and non-permanent/shallow water bodies (15 cm deep), respectively. The risks to aquatic organisms resulting from spray drift are summarized in Appendix I, Table 22. The risk quotients show that the LOC is exceeded for all organisms on an acute exposure basis and chronic exposure basis. For acute exposure, the refined RQs for freshwater invertebrate and fish were 1778 and 205, respectively when considering the acute SSD endpoint. The refined RQ for amphibians was 1090. The refined RQs for the most sensitive marine invertebrate endpoint and marine fish are 8060 and 9, respectively.

For the chronic exposure, the refined RQ for freshwater invertebrates determined using the freshwater mesocosm endpoint was 3000. The refined RQ for freshwater fish based on the chronic fathead minnow endpoint was 400. The refined RQ for amphibian was 2125. The refined RQ for marine invertebrates was 13,333. As the majority of bifenthrin partitions to the sediment, the chronic exposure scenario can be viewed as conservative to pelagic organisms.

For airblast sprayers, calculated buffer zones ranged from 50 to 75 metres and did not require additional spray mitiation measures.

However, initial spray buffer zones for field sprayers calculated based on fine ASAE spray quality were large and did not fully mitigate the risk to aquatic organisms. Therefore spray buffer zones were refined by setting restrictions on various spray application parameters: a minimum ASAE medium spray quality, an 8 km/h wind speed restriction and the requirement to use drift-reducing air induction nozzles. These restrictions are required on the product label. Calculated buffer zones for field sprayer adjusted according to windspeed and low drift nozzle modifiers ranged from 10 to 55 metres.

Runoff refinement: Exposure to runoff into a body of water directly adjacent to the application field was determined using the runoff 90th percentile of the EECs predicted by PRZM-EXAMS for an appropriate time-frame. The EECs were calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations were calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and one year). The 90th percentiles over each averaging period are reported as the EECs for that period. The Level 1 EECs for bifenthrin in water bodies with 15 cm and 80 cm depth were predicted by PRZM-EXAMS for five standard regional scenarios. The EECs used for calculation of the RQs were the highest values at the appropriate depth and appropriate time-frame. The highest detection (5.2 µg/L) in water monitoring data is within the range of the peak concentration predicted by modeling; consequently, this value was used along with the modelling numbers in the acute assessment for aquatic organisms (both 15 cm and 80 cm depths).

The RQs for exposure to bifenthrin through runoff are provided in Appendix I, Table 23. The RQs exceeded the LOC for majority of freshwater species (freshwater RQ = 5-2,500, marine RQ = 207-208), except *C. riparius*, Eastern oyster or sheepshead minnow. Therefore, freshwater invertebrates, fish, amphibians, and marine invertebrates in aquatic habitats directly adjacent to the application field are potentially at risk from exposure to runoff from a treated field. To reduce the risks of bifenthrin being carried in runoff to aquatic environment, in addition to precautionary label statements, a label statement for the construction and maintenance of a 10 metre vegetative filter strip between the area of application and waterbodies is required.

Other risks to aquatic organisms: Biological effects from pesticides can be a result of immediate direct toxic effects and also from effects that may be asserted after bioaccumulation; therefore, accumulated bifenthrin could potentially impact fitness and survival in biota. In the Alabama pond study discussed in the environmental fate section, bifenthrin residues were detected in different fish species and mussels more than one year after the last application to the adjacent field. A significant die-off of gizzard shads (approximately 1600 fish) was noted between mid-November 1986 and early March 1987. Gizzard shad samples collected during this period had bifenthrin residues ranging from 30 to 487 µg a.i./kg fish (average 312 µg a.i./kg fish). The mean bifenthrin residues of rainbow trout and bluegill sunfish sampled from highest treatment level with zero mortality were 137 µg a.i./kg and 196 µg a.i./kg, respectively. The mean bifenthrin residues of fish sampled from the treatment levels with 80 to 100% mortality were 546 µg a.i./kg and 625 µg a.i./kg, respectively. Bifenthrin residues in the field samples were comparible to residues observed in fish sampled from high mortality groups.

4.2.3 Incident reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system (including both mandatory reporting from the registrant and voluntary reporting from the public and other government departments) and the United States Environmental Protection Agency (USEPA) Ecological Incident Information System (EIIS).

Specific information regarding the mandatory reporting system regulations that came into force 26 April 2007 under the *Pest Control Products Act* can be found at https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/report-pesticide-incident.html.

There are no environmental incidents for bifenthrin in the PMRA database. As bifenthrin is registered in the United States, a review of the latest version of EIIS was completed. As of 5 October 2015, the EIIS database contained 38 incidents involving bifenthrin reported between 1992 and 2015. Six of these incidents are categorized as "unlikely" associated with exposure to bifenthrin. Of the remaining incidents, reports for various organisms including fish, plants, pollinators and birds were located in the USEPA EIIS database.

There were five incidents associated with bifenthrin involving fish mortality as a result of runoff. Three of these were classified as probable and occurred between 1994 and 1996. In 2005 and 2006 there were two fish mortality incidents where it was considered highly probable that the observed effects were a result of runoff of bifenthrin. A dead bird was also noted in the 2006 incident and was considered to be a result of exposure to granular formulated bifenthrin product for use on turf and residential sites. No incident involving birds from agricultural uses has been reported. These reported incidents support what was concluded in the risk assessment for bifenthrin and the need for mitigation.

The USEPA EIIS database included 19 incident reports of effects on plants occurring between 1999 and 2012. The 1999 incident was classified as probable that the effects observed were a result of application of bifenthrin to a rose plant. The remaining 18 plant incidents were classified as possible. Fourteen of the remaining plant incidents occurred in 2012 following application to plants of the same product which contained two active ingredients and a high percentage of formulants. Therefore, the formulants and other active ingredient have contributed to these fourteen incidents. No plant incidents were noted since 2012. As bifenthrin is still registered for direct application on various plants, such as garden vegetables, roses, ornamentals and agricultural crops in the United States without new incidents being reported in recent years, other unknown factors may have contributed to the historical plant incidents.

Seven pollinator incidents were reported in the USEPA EIIS associated with various bee species between 1992 and 2013. Four of the incidents were classified as either probable or high probable that the mortality observed resulted from exposure to bifenthrin.

For the remaining three incidents it was considered possible that bifenthrin contributed to the effects observed; however, other toxic active ingredients were also identified in the incident report. The observation of bee mortality incidents supports the conclusions of the current risk assessment and the need for mitigation measures to protect pollinators.

The PMRA concluded that the information from the incident reports is consistent with the known toxicity hazard of bifenthrin to fish and pollinators.

4.2.4 Use of Vegetative Filter Strips for Reducing Runoff to Aquatic Habitats

To reduce movement of bifenthrin into aquatic habitats via runoff, the PMRA is requiring that 10 metre vegetative filter strips be mandatory in areas of use.

Since 2008, the USEPA has required statements on all pyrethroid agricultural product labels requiring a 3.05 metre (10 ft) vegetative filter strip (VFS) composed of grass or other permanent vegetation between the field edge and aquatic habitats. No fish kill incidents have been reported in the United States since the implementation of these requirements. The absence of further incidences in relation to adherence/implementation of the VFS is uncertain, however, VFS's have been shown to reduce movement of contaminants, excess nutrients, soil and other detrimental components into aquatic systems.

In 2000, the province of Prince Edward Island (PEI) introduced buffer legislation which mandated vegetative filter strips for various land uses, including agricultural crops. The legislation required all agricultural fields that border water courses to maintain a 10 metre vegetative filter strip along the water edge. The minimum buffer width was increased to 15 metre in a 2008 amendment to PEI's Environmental Protection Act. Fields with steeper slopes (i.e. >5%) within 50 metres of the upland boundary of the 10 metre buffer and having no other mitigating management practices in place are required to have a 20 metre vegetative filter strip.

The EU has also adopted the use of VFS for sustainable use of pesticides. EFSA has proposed 20 metre VFS's for a number of crop protection products.

5.0 Value

5.1 Consideration of Benefits

5.1.1 Potatoes

Capture 240 EC controls wireworms which are important pests of potatoes that live in the soil and damage potato tubers. Growers identified the use of bifenthrin to control wireworms in potatoes as a high priority, both through the Canadian Grower Priority Database and the Canadian Minor Use Priority Setting Workshop.

At the time Capture 240 EC was registered in 2014, the last date of use for Thimet 15G, a product containing phorate that was used to control wireworms on potato, was in August 2015. Thimet 20-G, a new product containing this active ingredient, was registered in July 2015. As a result, bifenthrin to control wireworm on potato is no longer considered as a critical need due to the availability of a suitable alternative management tool for wireworms. Registered active ingredients for management of wireworms in potato are phorate and chlorpyrifos in mode of action group 1B and clothianidin in mode of action group 4A.

5.1.2 Raspberry

Capture 240 EC controls obliquebanded leafroller, orange tortrix, black vine weevil, obscure root weevil, clay coloured weevil and earwigs in raspberries. The pre-bloom application targets clay coloured weevil adults, which feed on raspberry buds in early spring. The post-bloom application targets black vine weevil, obscure root weevil, earwigs, obliquebanded leafroller and orange tortrix, which are contaminants of mechanically harvested raspberries.

Clay coloured weevils occur in the spring when it is too cold to use the one registered alternative, malathion (mode of action group 1B). Viable alternatives are available to control obliquebanded leafroller, including spinosad and spinetoram (mode of action group 5), *Bacillus thuringiensis* subspecies *kurstaki* (mode of action group 11) and methoxyfenozide (mode of action group 18). Weevils that occur at harvest, black vine weevil and obscure root weevil, are the most abundant harvest contaminants. Thiamethoxam is the only alternative for control of these pests. Though there are limited or no alternatives for earwigs and orange tortrix, these are not considered to be of significant concern because of the potential to register alternative active ingredients.

Considering the alternatives and impact caused by the insects, a critical need for bifenthrin remains to provide control of insect contaminants in raspberries, specifically obscure root weevil and black vine weevil, throughout the harvest season. As well, bifenthrin contributes to resistance management because it is a new mode of action (mode of action group 3A) for use against insect pests in raspberries.

5.2 Effectiveness Against Pests

Nine efficacy trials on potatoes were reviewed and demonstrated control of wireworms in potatoes at rates of 2.0–3.4 g a.i./100 m row.

Four field trials and three laboratory trials were reviewed to support control of listed pests in raspberries. The data demonstrated control of black vine weevil, obscure root weevil, clay coloured weevil and earwigs in raspberries at a rate of 112 g a.i./ha. Control of obliquebanded leafroller and orange tortrix in raspberries at a rate of 112 g a.i./ha was supported based on extrapolation from data provided on other lepidopteran pests. Application timing to control obliquebanded leafroller and orange tortrix activity in raspberries is similar to that of earwigs, black vine weevil and obscure root weevil.

5.3 Non-Safety Adverse Effects

No phytotoxicity was observed in any of the reviewed trials.

5.4 Supported Uses

Value information provided for the registration of Capture 240 EC supported control of wireworms in potato applied in furrow at the time of planting. However, there is presently not a critical need for this use because of the availability of other products to manage this pest. Therefore, this use is no longer supported.

Value information provided for the registration of Capture 240 EC supported control of clay coloured weevils, obliquebanded leafroller, orange tortrix, black vine weevil, obscure root weevil, and earwigs by foliar application in raspberries. Critical need has been established for foliar applications on raspberries in British Columbia to control clay coloured weevil and insects that are present as harvest contaminants, particularly the black vine and obscure root weevils.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*.

During the review process, bifenthrin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[6] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- The PMRA considers bifenthrin to be persistent, bioaccumalative and toxic (PBT) and it meets all the key criteria for a Track 1 substance under Canada's TSMP policy:
    - Bifenthrin is CEPA-Toxic equivalent.
    - Bifenthrin is persistent in the environment under most circumstances. Bifenthrin meets the TSMP Track 1 criteria for soil and aquatic systems.
    - Laboratory BCF values and the field BAF estimates exceeded the TSMP criteria of greater than 5000 for several fish species. One study showed that bifenthrin does not biomagnify in fish when only considering the diet under laboratory conditions (BMFs are <1.0). Under field conditions, however, sufficient information was provided to show that bifenthrin BAFs > 5000 are sustained long after applications. The field BAF values are a better representation of bioaccumulation under environmentally relevant conditions and consider multiple pathways of exposure.

Bifenthrin meets the Government of Canada's criteria for a Track 1 Substance under the Toxic Substances Management Policy adopted in 1995. These criteria are also outlined in the Persistence and Bioaccumulation Regulations (SOR/2000-107) which are used to define persistent or bioaccumulative under sections of the CEPA, 1999.

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[6] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

The PMRA's implementation of the TSMP is outlined in DIR99-03 describes how Track 1 substances will be managed. As this policy calls for the virtual elimination of Track 1 substances, the PMRA is proposing to phase out the use of bifenthrin over three years. The use of Capture 240 EC for control of wireworm on potato will be cancelled immediately, as of 31 December 2017 as an additional pest management tool has become available since the original registration. For the use of Capture 240 EC for the control of weevils on raspberries, a phaseout period of 3 years is proposed. Since no suitable alternative exists for raspberries, the PMRA has determined that bifenthrin meets the critical need criteria as outlined in DIR99-03 which would allow for its use on a time-limited basis with the imposition of restrictions on the registration designed to minimize the risks associated with its use. Specific risk mitigation measures designed to minimize the risks include: limiting the use to a small geographic location (raspberries in British Columbia), buffer zones to minimize spray drift, vegetative filter strip to reduce runoff, and prohibiting application during crop blooming period.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette.*[7] The list is used as described in the PMRA Notice of Intent NOI2005-01[8] and is based on existing policies and regulations including DIR99-03 and DIR2006-02[9], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade Bifenthrin Technical Insecticide does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

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[7] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[8] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New *Pest Control Products Act.*

[9] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for bifenthrin is adequate to define the majority of toxic effects that may result from exposure. In short-term and chronic studies on laboratory animals, the primary target of toxicity was the neurological system. There was no evidence of carcinogenicity in rats after longer-term dosing, and lung tumors in female mice and liver tumors in male mice were considered equivocal. Bifenthrin did not damage genetic material. Bifenthrin was not teratogenic in rats or rabbits, and did not cause any adverse effects on reproduction in rats. There was a low level of concern for increased sensitivity of the offspring; however, residual uncertainty remains regarding susceptibility of the young to the effects of pyrethroids. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Mixer, loader, applicators handling bifenthrin and workers re-entering treated areas are not expected to be exposed to levels of bifenthrin that will result in an unacceptable risk when bifenthrin is used according to label directions. The personal protective equipment on the product label is long-sleeved shirt, long pants, chemical resistant gloves, shoes plus socks and goggles during mixing, loading, application, clean up and repair.

The nature of the residues in plants and animals is adequately understood. The residue definition for enforcement is bifenthrin in plant products and in animal matrices. The use of bifenthrin on potatoes and raspberries does not constitute a risk of concern for chronic (cancer and non-cancer) or acute dietary exposure (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to support the established MRLs for this active ingredient, as found in the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage for MRLs

7.2 Environmental Risk

Bifenthrin meets the Government of Canada's criteria for a Track 1 Substance under the Toxic Substances Management Policy adopted in 1995. These criteria are also outlined in the Persistence and Bioaccumulation Regulations (SOR/2000-107) which are used to define persistent or bioaccumulative under sections of the *Canadian Environmental Protection Act* (CEPA), 1999. Under TSMP, substances meeting these criteria (Track 1) are persistent, bioaccumulative, toxic and primarily the result of human activity. Track 1 substances that cannot be managed successfully throughout their life cycle are targeted for vitual elimination from the environment, i.e., phase out of generation and uses.

Bifenthrin is moderately persistent to persistent in the terrestrial environment. The rate of transformation in the environment varies with environmental conditions such as soil type and climate. It is immobile and has a limited potential to leach to groundwater.

Bifenthrin may reach aquatic environments through spray drift and surface runoff. In the aquatic environment, it is expected to partition from the water layer and persist in the sediment. Therefore, continuous repetitive applications will increase the likelyhood of chronic risk to benthic communities as bifenthrin residues in the sediment increase overtime.

Bifenthrin is bioaccumulative and can accumulate in organisms under field conditions. There is some evidence that accumulated bifenthrin could potentially impact fitness and survival in aquatic organisms as observed in the field aquatic study.

Bifenthrin may pose a potential risk to pollinators, beneficial predatory and parasitic arthropods, small wild mammals, aquatic invertebrates, fish and amphibians.

Interim risk reduction measures are proposed to minimize environmental exposure during the phase out period and include the following: no-spray buffer zones to protect sensitive aquatic habitats from spray drift, and through the use of mitigative label statements to inform users of potential risks to the environment and indicate appropriate risk reduction measures.

7.3 Value

Value information demonstrated that Capture 240 EC controls wireworms in potatoes; however, bifenthrin is not a critical need because of the availability of products to manage this pest. Therefore, this use is no longer supported.

Value information provided for the registration of Capture 240 EC supported control of clay coloured weevils, obliquebanded leafroller, orange tortrix, black vine weevil, obscure root weevil, and earwigs by foliar application in raspberries. On raspberries, there is zero tolerance for insect harvest contaminants that affect the marketability of the fruit. Capture 240 EC is considered a critical need to manage harvest contaminants of raspberries in British Columbia because of the lack of suitable alternative products. As well, bifenthrin is a new mode of action for resistance management of these pests in raspberries.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing a time limited registration for the sale and use of Bifenthrin Technical Insecticide and Capture 240 EC, containing the technical grade active ingredient bifenthrin, to control certain pests in raspberries.

The evaluation of the additional environmental information found that bifenthrin meets the criteria for Track 1 substances under the TSMP. The PMRA's implementation of the TSMP is outlined in DIR99-03. This directive describes how Track 1 substances will be managed by the PMRA, and calls for the virtual elimination of Track 1 substances. For use of Capture 240 EC for control of weevils on raspberries, a phase out period of three years is proposed. Since no suitable alternative exists for raspberries, the PMRA has determined that bifenthrin meets the critical need criteria as outlined in DIR99-03 which would allow for its use on a time-limited basis with the imposition of restrictions on the registration designed to minimize the risks associated with its use. Specific risk mitigation measures designed to minimize the risks include:

limiting the use to a small geographical location (raspberries in British Columbia), buffer zones to minimize spray drift, vegetative filter strips to reduce runoff, and prohibiting application during crop blooming period. Therefore, registration for the use of Capture 240 EC on raspberries is granted for use only in British Columbia for three years beginning 1 January 2018 until 31 December 2020. The use of Capture 240 EC for control of wireworm on potato will be cancelled as of 31 December 2017

List of Abbreviations

°C	degrees Celsius
=	equal
>	greater than
<	less than
≥	greater than or equal to
±	plus or minus
↑	increase
↓	decrease
%	percent
♀	female
♂	male
λ	wavelength
ε	emittance
α	assimilation efficiency
μg	microgram(s)
μgL	microliter(s)
a.i.	active ingredient
abs.	absolute
ADI	acceptable daily intake
AHETF	Agricultural Handler Exposure Task Force
AGF	aspirated grain fraction
AOPWIN	model that estimates the gas-phase reaction rate for the reaction between the most prevalent atmospheric oxidant, hydroxyl radicals, and a chemical and calculates atmospheric half-lives for chemicals
app	application
appl.	Application
AR	applied radioactivity
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ASAE	American Society of Agricultural Engineers
ATPD	Area treated per day
BAF	bioaccumulation factor
BCF	bioconcentration factor
BCF_K	kinetic BCF
BCF_{KG}	kinetic BCF corrected for growth
BCF_{KGL}	kinetic BCF corrected for growth and lipid content
BCF_{SS}	steady state BCF
BMD	benchmark dose
$BMDL_{20}$	benchmark dose limit estimated for 20% effect
BMF	biomagnification factor
BMF_K	kinetic BMF
BMF_{KG}	kinetic BMF corrected for growth
BMF_{KGL}	kinetic BMF corrected for growth and lipid content
BMF_{SS}	steady state BMF
BP	biphenyl

BW	generic body weight
bw	body weight
bwg	body weight gain
C_{max}	maximum concentration
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CDN	Canadian
CEPA	*Canadian Environmental Protection Act*
CG	crop group
CI	confidence interval
cm	centimetre(s)
cm^2	centimetre(s) squared
cm^3	centimetre(s) cubed
CP	cyclopropyl
CSG	crop sub-group
d	day(s)
DAA	day(s) after application
DACO	data code
DFR	Dislodgeable foliar residue
DIR	directive
DNA	deoxyribonucleic acid
DNT	developmental neurotoxicity
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
dw	dry weight
EC	emulsifiable concentrate or European Commission
EC_{50}	effective concentration on 50% of the population
EDE	estimated daily exposure
EEC	estimated environment concentrations
EFSA	European Food Safety Authority
EIIS	USEPA Ecological Incident Information System
EP	end-use product
ERC	evaluation report
F_0	parental generation
F_1	first generation
FA	fraction of species affected
FC	food consumption
FDA	*Food and Drugs Act*
FIR	food ingestion rate
FMC	FMC Corporation
FOB	functional observation battery
g	gram(s)
G	granule
gal	gallon(s)
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detection

GC-MS	gas chromatography mass spectroscopy
ha	hectare(s)
HAFT	highest average field trial
HC_5	hazardous concentration to five percent of species
HDPE	high density polyethylene
Hg	mercury
HPLC	high performance liquid chromatography
hr	hour
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_d	soil-water partition coefficient
km	kilometre(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
kPa	KiloPascals
L	litre(s)
LAFT	lowest average field trial
lb	pound(s)
LC_{50}	lethal concentration 50%
LC/MS/MS	high performance liquid chromatography with tandem mass spectrometry
LD	lactation day
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	meter(s)
m^3	cubic metre(s)
MAS	maximum average score
Max.	maximum
mg	milligram(s)
min.	minute(s)
Min.	minimum
MIS	maximum irritation score
ml	millilitre(s)
M/L/A	mixer/loader/applicator
mm	millimeter(s)
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
MSD	mass selective detection or mass spectrometric detection
n	number
NA	not analysed
N/A	not applicable
NAFTA	North American Free Trade Agreement
NAWQA	US Geological Survey's National Water-Quality Assessment Program
NIOSH	National Institute for Occupational Safety and Health

nm	nanometre(s)
NM	not modelled
NMR	nuclear magnetic resonance
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
NOI	Notice of Intent
NZW	New Zealand white
OECD	Organisation for Economic Co-operation and Development
OH	hydroxy
P	parental generation
Pa	Pascal(s)
PBI	plantback interval
PCB	polychlorinated biphenyl
PCPA	*Pest Control Product Act*
PEI	Prince Edward Island
P*f*	processing factor
PH	phenyl
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	postnatal day
ppb	parts per billion
ppm	parts per million
PRAPeR	EFSA'a Pesticide Risk Assessment Peer Review unit
RAC	raw agricultural commodity
REI	restricted-entry interval
rel.	relative
ROLD	repeat oral low dose
RQ	risk quotient
RT_{25}	residual time to 25% bee mortality
RTI	retreatment interval
SC	soluble concentrate
SD	standard deviation
SOHD	single oral high dose
SOLD	single oral low dose
SSD	species sensitivity distribution
STMdR	supervised trial median residue
STORET	EPA Storage and Retrieval Data Warehouse
TAR	total applied radioactivity
TC	Transfer coefficient
TFP	trifluoro-1-propenyl-
TFP acid	cis-3-(2-chloro-3,3,3-trifluoroprop-1-en-1-yl)-2,2-dimethylcyclopropanecarboxylic acid
TER	toxicity exposure ratio

T_{max}	time to peak blood concentration
TP	transformation product
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
US	United States of America
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USGS	U.S. Geological Survey
UV	ultraviolet
VFS	vegetative filter strip
vs.	verses
wk	week(s)
WP	wettable powder
WSB	water soluble bag
wt	weight
w/w	weight per weight dilution

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ		Reference
Fish[1]	N/A	bifenthrin	GC-ECD	1 ppb		1755330
Soil	N/A	bifenthrin	GC-MS	10 ppb		1755362
	N/A	4'-hydroxy bifenthrin	LC/MS/MS	10 ppb		1755361
	N/A	TFP acid	LC/MS/MS	10 ppb		1755361
Sediment[2]	N/A	bifenthrin	GC-MS	0.1 ppb		1755356
Surface water	N/A	bifenthrin	GC-MS	0.1 ppb		1755362
	N/A	4'-hydroxy bifenthrin	LC/MS/MS	0.01 ppb		1755361
	N/A	TFP acid	LC/MS/MS	0.1 ppb		1755361
Air[3]	N/A	bifenthrin	GC-MS	0.5 $\mu g/m^3$		1755346
Plant	P-0757, P-1073	Bifenthrin	Enforcement: GC-ECD	0.05 ppm	Apples, strawberries	1762180; 1762256
	P-2132M	Bifenthrin	Data-gathering: GC-ECD	0.5 ppm	Apples, cottonseed, field corn (silage, stover, grain)	1762165
	P-2281M	Bifenthrin	Data-gathering: GC-ECD	0.01 ppm	Field corn (grain, meal, flour, oil, starch, grits)	1762171
	P-2550M	Bifenthrin	Data-gathering: GC-ECD	0.05 ppm 0.1 ppm 0.5 ppm	Field corn grain Field corn silage Field corn stover	1762179
	P-2763 (Revised 4/99)	Bifenthrin	Data-gathering: GC-ECD	0.05 ppm	Walnut (nutmeat), peanut (nutmeat, soapstock)	1762181
	FCC 0596	Bifenthrin	Data-gathering: GC-ECD or MSD	0.05 ppm	Tea (fresh, green, black)	1828905
	RAN-0140	Bifenthrin	Data-gathering: GC-ECD	0.05 ppm	Cottonseed	1762182
Animal (except fish)	P-1031 (Revised)	Bifenthrin	Enforcement: GC-ECD	0.02 ppm 0.10 ppm 0.05 ppm	Milk Fat Muscle, liver, kidney	1762177
	P-1843M (Revised)	Bifenthrin BP alcohol	Enforcement: GC-ECD or MSD	0.02 ppm 0.05 ppm	Muscle Fat, liver, gizzard	1762178
	RAN-0204M	Bifenthrin	Enforcement: GC-ECD	0.01 ppm	Eggs	1762176
	P-1703M	Bifenthrin	Data-gathering: GC-ECD	0.2 ppm	Milk fat	1762170
	P-2533M	4'-OH-bifenthrin	Data-gathering: GC-ECD	0.5 ppm	Fat	1762163
	P-1704M	BP alcohol	Data-gathering: GC-MSD	0.02 ppm 0.05 ppm	Milk Liver, kidney, muscle, fat	1762172
		BP acid		0.05 ppm	Liver, kidney, muscle, fat	
	RAN-0203M	BP alcohol	Data-gathering: GC-MSD	0.01 ppm	Eggs	1762167
	P-1883M	TFP acid	Data-gatheringGC-MSD	0.05 ppm	Liver	1762173

[1] For 4'-hydroxy bifenthrin and TFP acid, the corresponding methods for cow fat can be used.

[2] For 4'-hydroxy bifenthrin and TFP acid, the corresponding methods for soil can be used.

[3] Bifenthrin is also found in air, for which the method was provided under this DACO since there is no distinct DACO for air.

Table 2 Toxicity Profile of Capture 240 EC Containing Bifenthrin

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons.)

Study Type/Animal/ PMRA #	**Study Results**
Acute Toxicity Studies (Capture 2EC formulation used as surrogate for listed toxicity studies)	
Acute oral toxicity Sprague-Dawley rats PMRA #1762133	LD_{50}: (undiluted) ♂ = 173 mg/kg bw ♀ = 159 mg/kg bw Combined = 167 mg/kg bw High acute toxicity
Acute dermal toxicity NZW rabbits PMRA #1762134	LD_{50} > 2000 mg/kg bw Low acute toxicity
Acute inhalation toxicity (whole body) Sprague-Dawley rats PMRA #1762135	LC_{50}: ♂ = 1.6 mg/L ♀ = 2.3 mg/L Combined = 1.9 mg/L Slight acute toxicity
Dermal Irritation NZW rabbits PMRA #1762137	MAS = 1.3 MIS = 1.4 (24h) Slightly irritating
Eye Irritation NZW rabbits PMRA #1762136	MAS = 3.9 MIS = 9.7 (1h) Minimally irritating
Dermal sensitization (Buehler test) Hartley guinea pigs PMRA #1762138	Sensitizer (inadequate study)

Table 3 Toxicity Profile of Technical Bifenthrin

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted)

	Study Results
Toxicokinetic Studies	
Metabolism Excretion (gavage) Sprague-Dawley rats (bile duct-cannulated) PMRA #1755390	Bile duct-cannulated rats were dosed with single oral doses of bifenthrin. Excreta and tissues were assayed to determine route of excretion and the nature of metabolites. Total oral absorption was estimated to be about 50% or 36% in female and male rats respectively. Feces excretion: 25% ♂/ 49% ♀; biliary excretion:19% ♂/ 30% ♀; urinary excretion: 11% ♂/ 15% ♀. Gut microflora had minimal impact on bifenthrin degradation. Bifenthrin metabolites in feces were the result of biliary excretion. The primary metabolites were OH-Me-bifenthrin , 4'-OH-bifenthrin and polar metabolites.
Distribution Excretion (gavage) Sprague-Dawley rats PMRA #1755391	Male and female rats were given, by oral gavage, a single radiolabelled bifenthrin. Excreta were monitored for 7 days. Seven days after dosing, rats were killed and tissues assayed for radioactivity. Minimal amounts found in tissues, greatest amount found in fat. ♀ exposed to the alcohol labeled ^{14}C-bifenthrin had the greatest amount in fat (twice as much as ♂ and animals exposed to the acid labeled ^{14}C-bifenthrin). The primary route of excretion was via feces (76-84%). Most of the radioactivity was excreted in feces and urine by 48 hours. Excretion times were similar for all groups (majority excreted 8-48 hours post dose), with the exception of ♀ exposed to the alcohol labeled ^{14}C-bifenthrin (majority excreted 12-48 hours post dose). Unchanged bifenthrin was the major product found in feces and urine (37-46% ♂/ 28-47% ♀). Unidentified metabolites amounted to 24-27% ♂/ 22-40% ♀. Amount metabolised was similar between labeled moieties, however ♀ exposed to the alcohol labeled ^{14}C-bifenthrin had a larger amount metabolised (40% vs 22-27% in other groups) and less recovered as unchanged bifenthrin (28% vs 37-47% in other groups). **Supplemental: Urinary metabolites not characterized, metabolites not identified.**
Distribution Metabolism Excretion (gavage) Sprague-Dawley rats	Animals were dosed with radiolabeled bifenthrin as a single low or high dose, or dosed with a low dose for two weeks. Minimal amounts found in tissues, largest administered dose found in fat of single high-dose ♀.

	Study Results
PMRA #1755392	Feces was the primary route of excretion (68.9-82.8% ♂/ 94.0-96.2% ♀). Most of the administered dose was recovered by 72 hours. Unchanged bifenthrin was the major product found in feces (17.2 - 44.2% of the administered dose). Twelve other metabolites, derived from hydrolysis and oxidation of bifenthrin were also detected. These included 4'-OH-hydroxy-methyl-bifenthrin; 3'-OH-hydroxy-methyl-bifenthrin, hydroxy-methyl-bifenthrin, 4'-OH-bifenthrin, 3'-monomethyl-catechol-bifenthrin and 4'-monomethyl-catechol-bifenthrin along with the hydrolytic and oxidative-hydrolytic products of bifenthrin including biphenyl alcohol, 4'-OH-biphenyl alcohol, biphenyl aldehyde, biphenyl acid, TFP acid hydroxymethyl-TFP acid. Unknown metabolites (three) found in the feces ranged between 0.2 - 3.6% of the total administered dose. Total organosoluble residues of the urine ranged from 10.6 - 17.6% of the administered dose. Unchanged bifenthrin was a negligible product (0.1% possibly due to faecal contamination). The urinary metabolites from hydrolysis and hydrolysis-oxidation products of bifenthrin included TFP acid, hydroxymethyl-TFP acid, biphenyl alcohol, 4'-OH-biphenyl alcohol, 3'-OH-biphenyl alcohol, 3'-monomethyl-catechol-biphenyl alcohol, 4'-monomethyl-catechol-biphenyl alcohol, biphenyl acid, 4'-OH-biphenyl acid and 4'-hydroxy-biphenyl acid methyl ester. Four unidentified metabolites combined did not exceed 1% of the dose. A maximum level of polar, water soluble degradates amounted to 5.5% of the dose.
Metabolism Sprague-Dawley rats (gavage) PMRA #1755393 and 1755394	Groups of male rats were given either a low (Group A, B) or high dose (Group C, D) and either blood samples taken at intervals (A, C) or animals were killed at intervals (B, C) and tissues sampled. Radioactivity levels in the blood of Group A animals peaked at 4 hours (0.66 ± 0.13 μg/ml). Levels peaked at 6 hours (3.29 ± 1.62 μg/ml) in Group C animals. Radioactivity was still detected in both groups at 72 hours. For the sacrificed animals, the highest radioactivity levels were observed at 4 hours (Group B) and 6 hours (Group D). Radioactivity levels within the low dose groups (Groups A and B) were comparable with the exception of the peak levels at 4 hours. The levels observed in Group B was more than 2-fold greater than that observed in Group A (1.88 ± 1.09 μg/ml in Group B vs. 0.66 ± 0.13 μg/ml in Group A). There was a greater difference in radioactivity levels between the high dose groups (Group C and D). Radioactivity at 24 hours post dose was comparable, but there was large difference in levels observed at 3, 6 and 10 hours. Particularly at 6 hours when peak levels were observed (8.78 ± 2.89 μg/ml in Group C vs. 3.29 ± 1.62 μg/ml in Group D). In Group B, a large amount of unchanged bifenthrin was detected in the plasma (0.103 ppm and 0.677 ppm at 2 and 4 hours post dose, respectively. At 10 hours, plasma levels decreased to 0.128 ppm. In Group D, unchanged bifenthrin was also detected, but to a lesser extent

	Study Results
	than Group B (0.734 ppm at 3 hours post dose, peaking to 3.29 ppm at 6 hours and declining to 0.13 ppm by 24 hours). The major metabolites were biphenyl acid (0.037-0.317 ppm in Group B and 0.502-1.3 ppm in Group D) and biphenyl alcohol (0.091-0.615 ppm in Group B and 0.134-2.86 ppm in Group D). Unchanged bifenthrin and its metabolites declined in plasma over time with a corresponding increase in protein-bound residues of the total radiolabel.
Kinetics Metabolism Sprague-Dawley Rat (gavage) PMRA #1755395	Female rats were given a low dose of radiolabelled bifenthrin for 70 days. Animals were killed and tissues analysed at intervals after the initiation of dosing. Tissue samples were collected for up to 85 days after the last dose of bifenthrin. Sciatic nerve tissue was sampled in a subset of these intervals (day 56 to termination of study). Radioactivity levels in plasma and whole blood was relatively low, starting at 0.01 µg/ml and 0.01 µg/g, respectively, and peaking at 0.06 µg/ml (day 70) and 0.06 µg/g (days 49-70), respectively. Elimination from the plasma was relatively rapid with the concentration of ^{14}C-bifenthrin dropping to 0.02 and 0.01 µg/ml at days 73 and 78, respectively. Elimination from whole blood was slower with the concentration of ^{14}C-bifenthrin dropping to 0.03 and 0.01 µg/g on days 78 and 99, respectively. Radioactivity concentrations reached non-detectable levels after day 78 and 113 for plasma and whole blood, respectively. The highest concentrations of radioactivity were found in the fat (9.62 µg/g at day 70) and skin (2.06 µg/g at day 73) with half-lives of 51 and 50 days, respectively. The organs with higher fat concentrations (sciatic nerve and ovaries) had longer half -lives (42 and 37 days, respectively) and higher peak radioactivity concentrations (3.25 and 1.69 µg/g, respectively) while other organs (liver and kidney) had shorter half- lives (19 and 28 days, respectively) and lower peak concentrations of radioactivity (0.4 and 0.32 µg/g, respectively). Radioactivity detected in fat was predominantly unchanged bifenthrin (72%-85% of total radioactivity between days 7 and 155) with 3 metabolites making up the rest of the radioactivity detected. One metabolite was found in higher concentrations than the others, and percent of radioactivity detected increased steadily up until study termination, possibly indicating that metabolic processes continue to occur in the fat to facilitate excretion (metabolite is slightly more polar than unchanged bifenthrin). **Potential for bioaccumulation**
Metabolism and excretion Sprague-Dawley Rat (gavage)	Groups of male and female rats were gavage dosed with either a single low bifenthrin dose or with a high dose of bifenthrin. Groups of rats were also dosed with low and high doses for 14 days of a high dose of bifenthrin.

	Study Results
PMRA #1755399 and 1755403	Less than 1% of administered ^{14}C was detected in expired air in preliminary study, therefore, expired air not monitored in main study. Primary route of excretion was via feces (71.15-83.5%) and urine (9.37-14.46%). Ranges are in both sexes and all doses after 168 hours. Majority of radioactivity excreted within the first 48 hours in all dose groups (66.9-80.6% in feces, 7.26-11.27% in urine). Feces elimination slightly slower in SOHD animals (68.79% and 66.09% at 48 hours in ♂ and ♀, respectively). Highest concentrations seen in fat and skin. Fat: SOLD-1.12 and 1.18 ppm; ROLD-1.44 and 1.27; SOHD-7.66 and 15.60 for ♂ and ♀, respectively. Skin: SOLD-0.14 and 0.18; ROLD-0.19 and 0.21; SOHD-0.73 and 2.16 for ♂ and ♀, respectively. Percent of administered dose in tissue ranged from 0.05-0.10% in fat, and <0.01-0.03% in skin. Feces metabolites excreted primarily as unchanged bifenthrin (21.80-39.22% of administered dose) and non-conjugates (including: hydroxymethyl-bifenthrin, 4'-OH-bifenthrin, 3'-OH-hydroxymethyl-bifenthrin, 4'-OH-hydroxy-methyl-bifenthrin 3'-monomethyl-catechol-bifenthrin and 4'-monomethyl-catechol-bifenthrin, dimethoxy-bifenthrin and 4'-methoxy-bifenthrin. Hydrolytic products related to mono- and dihydroxylated bifenthrin were also detected which included 4'-OH-biphenyl alcohol, 4'-OH-biphenyl alcohol, dimethoxy-biphenyl acid, dimethoxy-biphenyl alcohol, 4'-methoxy biphenyl alcohol and biphenyl alcohol, TFP acid, cis and trans-hydroxymethyl-TFP acid). In urine, no radioactivity was detected as unchanged bifenthrin in ♀ while very little (0.01% of administered dose) was detected in SOHD ♂ only. The major metabolites in alcohol labeled samples (♂) were 4'-OH BP acid (1.65 – 2.15% of administered dose), BP acid (0.90 – 1.07% of administered dose), 4'-OH BP alcohol (0.31 – 0.42% of administered dose) and dimethoxy BP alcohol (0.26 – 0.34% of administered dose); and in acid labeled samples (♀) the major metabolites were TFP acid (1.63 – 2.09% of administered dose), cis-OH-methyl TFP acid (0.78 – 1.48% of administered dose) and trans-OH-methyl TFP acid (0.58 – 0.78% of administered dose).
Absorption Distribution Excretion (gavage) Sprague-Dawley Rat PMRA #1755405	In a preliminary study, rats were dosed with radiolabeled bifenthrin and expired air collected. Very low levels of radioactivity were collected in expired air. Based on this finding, expired air was not collected in the main study. In the main study, male and female rats were dosed with radiolabelled bifenthrin, either as a single low dose, a repeated (14 days) low dose, or

	Study Results
	a single high dose. The majority of radioactivity was collected in feces and urine. There were no difference seen between sexes and dose levels. After 168 hours 73-83% of administered dose excreted in feces versus 13-20% in urine (SOLD). For ROLD the range of excretion was 66-73% (feces) and 18.36-25.01% (urine), and for SOHD it was 69-71% (feces) and 22% (urine). Most of the radioactivity was excreted within 48 hours, but was slower in the SOHD. SOLD: 64-78% (feces), 11-17% (urine); ROLD: 50-69% (feces), 14-21% (urine); SOHD: 43-56% (feces), 18-15% (urine). Tissue distribution: SOLD – individual tissue residues were relatively low (0.004-1.502 ppm) and similar between sexes. Tissues with the most residue were fat > skin > ovaries > pancreas > lungs (♂) > liver. Total residues in all tissue ranged from 1.76-8.35% of administered dose (AD). ROLD – similar residues and distribution compared to SOLD. Residues for individual tissues ranged from 0.009-2.532 ppm while total residues ranged from 1.64-5.45% of AD. Tissue distribution was fat > pancreas > ovaries > skin > liver in ♀ and fat > pancreas > prostate > liver > skin in ♂. SOHD – tissue residues were higher in ♀. Individual tissue residues ranged from 0.087-23.895 ppm in ♀ and 0.036-4.380 ppm in ♂. Total tissue residues were similar between sexes and ranged from 1.02-6.65% of AD. Tissue distribution was fat > skin > ovaries > pancreas in ♀ and fat > skin > liver > prostate in ♂.
Kinetics - in vitro Long-Evans rat human PMRA# 2501803	In vitro metabolic rate constants in rat and human pooled hepatic microsomes were determined using several concentrations of bifenthrin. Km and Vmax in rat hepatic microsomes: Km = 5.42 µM (3.25-8.52 µM) Vmax = 0.64 nmol/min/mg (0.56-0.74 nmol/min/mg) Vmax/Km = 0.12 ml/min/mg Intrinsic clearance from rat and human liver microsomes : CL_{int} (rat) = 224 ± 20 ml/min/kg bw CL_{int} (human) = 20 ± 6 ml/min/kg bw In the rat, the following P450 isoforms are involved in the metabolism of bifenthrin: CYP1A1, CYP1A2, CYP2B1, CYP2C6, CYP2C11, CYP2C12, CYP3A1, CYP3A2. In the human, the following P450 isoforms are involved in the metabolism of bifenthrin: CYP2C8, CYP2C9*1, CYP2C9*2, CYP2C9*3, CYP2C19.
In vitro comparative metabolism	To examine the relative metabolic capabilities of mice and rats, liver microsomes were prepared from male and female mice and male rats. Microsomes were incubated with bifenthrin for 0, 15, 30, or 60

	Study Results
Swiss-Webster Mouse Sprague-Dawley Rat PMRA #1755402	minutes. Recovery of radioactivity: Incubation time had no effect on radioactivity recovered in supernatant or pellet washes in all samples. Radioactivity recovered in the pellet increased from 0.1-1.2 % of the administered dose at 0 minutes to 2.1-5.2% of administered dose at 60 minutes, in a time dependent manner in all samples. Metabolism was not extensive. At 0 minutes, 78.1-88.6% administered radioactivity was unchanged bifenthrin, <15% were metabolites. At 60 minutes, 60.7-80.8% administered radioactivity was unchanged bifenthrin, <19% were metabolites. Identified metabolites 4-OH bifenthrin (0.55-3.44% and 2.25-5.95% for 0 and 60 minute incubation times, respectively) and BP acid (0-3.29% and 0-3.27% for 0 and 60 minute incubation times, respectively) were formed by ring hydroxylation and scission of bifenthrin, respectively. Metabolic activity between species was believed to be in the order male mouse > female mouse > male rat. Total identified and unidentified metabolites, respectively: cyclopropyl ring labelled bifenthrin-male mouse (8.02 and 15.97%), female mouse (3.48 and 2.17%), male rat (1.81 and 11.11%); phenyl-ring labelled bifenthrin-male mouse (3.84 and 23.86%), female mouse (5.58 and 5.79%), male rat (0.14 and 6.63%).
Acute Toxicity Studies	
Acute oral toxicity Sprague-Dawley Rat PMRA #1755500	LD_{50}: (in corn oil) ♂ = 55.5 mg/kg bw ♀ = 53.4 mg/kg bw Combined = 54.5 mg/kg bw High toxicity
Acute oral toxicity Swiss Webster Mouse PMRA #1755501	LD_{50}: (in corn oil) ♂ = 43.5 mg/kg bw ♀ = 42.5 mg/kg bw Combined = 43.0 mg/kg bw High toxicity
Acute oral toxicity Sprague-Dawley Rat PMRA #1755502	LD_{50}: (in corn oil) ♂ = 70.1 mg/kg bw ♀ = 53.8 mg/kg bw Combined = 56.7 mg/kg bw High toxicity
Acute oral toxicity Sprague-Dawley Rat	LD_{50}: (undiluted) ♂ = 168.4 mg/kg bw ♀ = 210.4 mg/kg bw

	Study Results
PMRA #1755508	Combined = 186.1 mg/kg bw High toxicity
Acute dermal toxicity Sprague-Dawley Rat PMRA #1755499	LD_{50}: ♂ > 2000 mg/kg bw ♀ > 2000 mg/kg bw Combined > 2000 mg/kg bw Low toxicity
Acute dermal toxicity New Zealand White Rabbit PMRA #1755498	LD_{50}: ♂ > 2000 mg/kg bw ♀ > 2000 mg/kg bw Combined > 2000 mg/kg bw Dermal effects: Irritation, desquamation Low toxicity
Acute inhalation toxicity (nose-only) Sprague-Dawley Rat PMRA #1755497	LC_{50}: ♂ = 1.1 mg/L ♀ = 0.8 mg/L Combined = 1.01 mg/L Slight acute toxicity
Eye Irritation New Zealand White Rabbit PMRA #1755496	Non-irritating
Skin Irritation New Zealand White Rabbit PMRA #1755495	No dermal irritation observed. Non-irritating
Skin sensitization - Maximization Test Guinea Pig PMRA #1755492	Sensitizer
Skin sensitization - Buehler Method Hartley Guinea Pig	Non-sensitizer

	Study Results
PMRA #1755494	
Short-Term Toxicity Studies	
28-day oral toxicity (diet) Range-Finding Swiss Webster Mouse PMRA #1755478	Study 1: ≥21.6/28.3 mg/kg bw/day – (♂,♀): ↓abs. brain wt., ↓rel. brain wt. Study 2: ≥108.0/120.4 mg/kg bw/day – (♂; ♀): tremors; ↓FC (♀, wk 1-3) ≥112.8/186.7 mg/kg bw/day – (♀): mortality, ↓FC, ↑rel. liver wt. ≥142.8/217.3 mg/kg bw/day – (♂):↑bwg; (♀) overall ↓bwg, ↓FC 164.1/120.5 mg/kg bw/day – (♂/♀): ↓FC; (♂) mortality; (♀): ↓bw, overall ↑bwg Supplementary: Range-finding
28-day oral toxicity (diet) Range-Finding Sprague-Dawley Rat PMRA #1755477	≥5.38/5.42 mg/kg bw/day – (♂): ↑relative brain and relative kidney wt ≥21.9/21.6 mg/kg bw/day – (♂/♀): tremors (≥day 2); (♂): ↓bw and bwg; (♀): ↓FC 34.5/32.6 mg/kg bw/day – (♂/♀): mortality, clonic convulsions, ↓bw and bwg, ↓FC; (♂s): ↓adrenal wt, ↓testicular wt, ↑relative adrenal wt, brain and kidney wts; (♀):↑relative brain, kidney, and liver wt Supplementary: Range-finding
90-day oral toxicity (diet) Sprague-Dawley Rat PMRA #1755483	NOAEL = 3.8/4.3 mg/kg bw/day LOAEL = 7.5/8.5 mg/kg bw/day; based on (♂/♀): tremors (days 3 to 5) Recovery period: tremors ceased within three days of the cessation of dosing
90-day oral toxicity (capsule) Beagle Dog PMRA #1755479, 1923291, 1923290, 1923289	NOAEL = 2.5 mg/kg bw/day LOAEL = 5 mg/kg bw/day; based on (♂/♀): tremors; (♀): ataxia, cyclic activity with signs of estrous
12-month oral toxicity (capsule) Beagle Dog	NOAEL = 1.5 mg/kg bw/day LOAEL = 3 mg/kg bw/day; based on (♂/♀): tremors; (♂): ↑serum Na^+, delayed estrous

	Study Results
PMRA #1755481, 19293292	
21-day dermal toxicity Sprague-Dawley Rat PMRA #1755474	NOAEL = 50 mg/kg bw/day Systemic LOAEL = 100 mg/kg bw/day; based on (♂/♀): tremors, staggered gait; (♂): erythema; (♀): skin ulceration, exaggerated hindlimb flexion, ↓tail flick latency Dermal effects were noted at all doses, with severity increasing with dose; (♂/♀): desquamation, hyperplasia, hyperkeratosis, eschar, clinical signs of cutaneous paraesthesia (vocalization, thrashing in cage, lying on back)
21-day dermal toxicity New Zealand White Rabbit PMRA #1755475	≥25 mg kg bw/day: Erythema 500 mg/kg bw/day: – (♂/♀): Tremors, loss of muscle coordination; (♀): ↑ abs. and rel. liver wt Supplementary: Lack of histopathology on nervous tissue (collected but not examined). Hematology, clinical chemistry, gross necropsy, and pathology data not reported.
Chronic Toxicity/Oncogenicity Studies	
Oncogenicity (diet) Swiss Webster Mouse PMRA #1755453, 1755387, 1755461, 1755462, 1755463, 1755464, 2376129	NOAEL not observed LOAEL = 7.6/10 mg/kg bw/day; based on (♂): tremors, bilateral germinal epithelial degeneration of the testes; (♀): bronchioalveolar adenocarcinomas and adenomas **Equivocal evidence of carcinogenicity**
Chronic/Oncogenicity (diet) Sprague-Dawley Rat PMRA #1755450, 1755452, 1755465, 1755449	NOAEL = 2.3 mg/kg bw/day LOAEL = 4.7 mg/kg bw/day; based on ↑bw, ↑rel. liver, ↑rel. kidney wt.; (♀): tremors **Non-carcinogenic**
Genotoxicity Studies	
Bacterial Reverse Mutation Assay *Salmonella typhimurium* TA98, TA100, TA1535, TA1537, TA 1538 PMRA #1755423	Negative
Bacterial Reverse	Negative

	Study Results
Mutation Assay *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and *E. coli* WP2 *uvr*A PMRA #1755428	
Bacterial Reverse Mutation Assay *Salmonella typhimurium* TA98, TA1535 and TA1537 PMRA #1755429	Negative
Chromosomal Aberrations CHO cells PMRA #1755415	Negative
Chromosomal Aberrations CHO cells PMRA #1755416	Negative (non-activated) Inconclusive (activated) – s.s. positive response at 20µg/ml but not at higher doses. No dose response.
Morphological Transformation BALB/3T3 mouse embryo cells PMRA #1755417	Negative
Fluctuation Assay Mouse lymphoma L5178Y cells PMRA #1755418	Negative
Mouse Lymphoma Mutagenesis Assay L5178Y TK+/-	Negative

	Study Results
PMRA #1755421	
Unscheduled DNA Synthesis Sprague-Dawley Rat hepatocytes PMRA #1755396	Negative
Unscheduled DNA Synthesis Sprague-Dawley Rat hepatocytes PMRA #1755397	Equivocal @ 2.0 μl/ml
Mouse Lymphoma Mutagenesis Assay L5178Y TK+/- PMRA #1755413	Positive ± S9
Sister Chromatid Exchange Assay CHO cells PMRA #1755414	Negative
In vivo Cytogenetics Assay (Chromosome Aberration) Sprague-Dawley rat bone marrow PMRA #1755408	Negative
Mammalian Erythrocyte Micronucleus Test ICR mouse bone marrow PMRA #1755410	Negative
In vivo Unscheduled DNA Synthesis Test – gavage	Negative

	Study Results
Sprague-Dawley rat hepatocytes PMRA #1755406	
Gene Mutation Assay CHO cells PMRA #1755388	Negative
Unscheduled DNA Synthesis Adult ♂ Wistar/WU rat hepatocytes PMRA #1755389	Negative
Developmental/Reproductive Toxicity Studies	
Multi-generation reproductive toxicity (diet) Sprague-Dawley rat PMRA #1755448	**Parental Toxicity** NOAEL = 3 mg/kg bw/day LOAEL = 5 mg/kg bw/day; based on **(**♀**):** tremors P, F1dams, clonic convulsions; (♂): ↓FC (F1), ↓bw (P), ↓bwg (P, F1), ↑rel. brain weight (P), ↓bw in P and F1 dams **Reproductive Toxicity** NOAEL = 5 mg/kg bw/day LOAEL = Not observed; (♀): equivocal ↑ litter incidence of stillborn pups possibly related to heating failure **Offspring Toxicity** NOAEL = 5 mg/kg bw/day LOAEL = Not observed
Developmental toxicity (diet) Sprague-Dawley rat PMRA #1755431	**Maternal Toxicity** NOAEL = 7.1 mg/kg bw/day LOAEL = 15.5 mg/kg bw/day; based on (♀): tremors, splayed hindlimbs, hypersensitivity to sound, piloerection, ↓bwg, ↓rel. FC **Developmental Toxicity** NOAEL = 15.5 mg/kg bw/day LOAEL not observed **No evidence for sensitivity of the young or malformations**
Developmental toxicity (gavage) Sprague-Dawley Rat PMRA #1755432, 2376130	**Maternal Toxicity** NOAEL = 1.0 mg/kg bw/day LOAEL = 2.0 mg/kg bw/day; based on (♀): tremors **Developmental Toxicity** NOAEL = 1.0 mg/kg bw/day

	Study Results
	LOAEL = 2.0 mg/kg bw/day; based on (♂/♀): hydroureter without hydronephrosis (variation) **No evidence for sensitivity of the young or malformations**
Developmental toxicity (gavage) New Zealand White Rabbit PMRA #1755430	**Maternal Toxicity** NOAEL 2.67 mg/kg bw/day LOAEL 4.0 mg/kg bw/day; based on (♀): head and forelimb twitching **Developmental Toxicity** NOAEL ≥ 8.0 mg/kg bw/day LOAEL not observed **No evidence for sensitivity of the young**
Neurotoxicity Studies	
Acute-Delayed Neurotoxicity (gavage) Hen PMRA #1755447	**LD$_{50}$ Determination:** LD$_{50}$ > 5000 mg/kg bw (in corn oil) ≥ 1250 mg/kg bw: – (♀): unsteadiness, inability to walk, wing-dropping, twitching of head and neck. All birds recovered after 72 hours post-dose. **Neurotoxicity Determination:** Initial dose (Day 0) – (♀): unsteadiness, difficulty standing, jerking head movements (all animals in test groups). All birds recovered by day 4 except 2 in last dose group. ↓FC Second dose (Day 21) – (♀): mortality, ↓bw, unsteadiness, difficulty standing, jerking head movements, violent head and leg movements and trembling (all treated animals 4 days after repeat dose). Surviving birds recovered by day 28. ↓FC more marked effect after repeat dose. **No evidence of delayed neurotoxicity.** There were no neuropathology findings, clinical effects were transient. **Supplementary: limited statistical analysis, lack of neurochemical assessment**
Acute-Delayed Neurotoxicity (Tilting-Plane Test) (gavage) (non-guideline) COBS/Wistar Rat PMRA #1755444	Irwin dose range-finding study (in corn oil) 10 mg/kg bw – (♂): moderately abnormal body carriage (hunched posture) and slightly abnormal gait , tremors, apathy, and reduced grooming 30 mg/kg bw – (♂): tremors, abnormal body carriage and gait, and respiratory depression, mortality, CNS depression and increased salivation, respiratory depression, clonic convulsions, abnormal body carriage, ptosis, greasy looking fur, paralysis, severe tremors and twitches.

	Study Results
	Minimum effective dose eliciting severe neurological signs = 30 mg/kg/day (dose selected for tilting-plane test). No neurohistopathology was conducted. Tilting-plane test (in corn oil) 30 mg/kg bw – (♂/♀): slight increase in the mean angle of slip on day 2, mortality; (♀): stereotyped grooming and greasy appearance of fur, ↓bw. No neurohistopathology was conducted. **No evidence of delayed neurotoxicity.**
Acute Oral Neurotoxicity (gavage) Non-Guideline Motor Activity Long-Evans Rats PMRA#2007554	4 hours post exposure (time of peak effect) with 100% (Z, 1R cis) isomer: ≥ 3 mg/kg bw – (♂): ↓ mean total motor activity (in corn oil). Using an exponential dose-response model, the following benchmark dose (BMD) values for motor activity were derived: BMD_{20} = 4.1 mg/kg bw $BMDL_{20}$ = 2.6 mg/kg bw Note: The $BMDL_{20}$ was selected based on the normal variability of motor activity in historical control rats (i.e., 9.6% to 26%) (PMRA#2351167).
Acute oral neurotoxicity (gavage) Sprague-Dawley Rats PMRA #1755440	NOAEL = 35 mg/kg bw LOAEL = 75 mg/kg bw; based on clinical findings – (♂): decreased feces; (♀): mortality, twitching, abdominogenital staining, clonic convulsions, chromorhinorrhea, tremors. All clinical signs resolved after day 2. FOB findings – @ 6-8 hours post dose – (♂/♀): whole body tremors, tense/rigid during handling; (♂): abnormal mobile posture, uncoordinated movement/ataxia; splayed hindlimbs; (♀): convulsions, unusual posture. @ end of day 0 – (♂/♀):whole body tremors; (♂):localized spasms/twitching, staggered gait, abnormal posture, uncoordinated movement/ataxia, splayed hindlimbs, ↓ landing foot-splay values; (♀):increased activity; decreased activity, convulsions, walking on toes, unusual immobile posture. Motor activity – (♂): decreased; (♀): increased.
28-day neurotoxicity Range finding (diet) Sprague-Dawley Rat PMRA #1755443	100 ppm – (♀): tremors 200 ppm – (♂/♀): tremors; (♂): twitching, unthriftiness, dehydration. 300 ppm – (♂/♀): tremors; (♂): twitching , unthriftiness , dehydration, ↓bw; (♀): mortality, ↓bwg, chromorhinorrhea, hypersensitivity to sound, splayed hindlimbs, abdominogenital staining

	Study Results
90-day Neurotoxicity (diet) Sprague-Dawley Rat PMRA 1755438	NOAEL 2.9 mg/kg bw/day LOAEL 6.0 mg/kg bw/day; based on (♂/♀): tremors, twitching. FOB – (♀): tremors, ↓hindlimb grip strength
Dietary feasibility and Range-Finding for DNT study Sprague-Dawley Rat PMRA# 1755433	9.3/22.5 mg/kg bw/day: (♀): slight to moderate whole body tremors Cmax(milk) on LD 11 for all groups. Residue levels increased in somewhat linear fashion with increased dietary concentration. Maternal plasma levels similar on LD 4 and 22. Plasma levels increased more than milk levels with increasing dose. Offspring plasma levels, dose response and time course profiles similar to maternal levels.
Developmental Neurotoxicity (diet) Sprague-Dawley Rat PMRA #1755435, 2376131	**Maternal Toxicity** NOAEL = 3.6 mg/kg bw/day LOAEL = 7.2 mg/kg bw/day; based on (♀): tremors, ↑ grooming, clonic convulsions. **Offspring Toxicity** NOAEL = 3.6 mg/kg bw/day LOAEL = 7.2 mg/kg bw/day; based on ↑ mean grooming counts (♀ at PND 21), ↓ total motor activity, ↑ T_{max} acoustic startle (♀ at PND 20)
Impurity Studies	
Bacterial Reverse Mutation Assay FMC 102032 (Bifenthrin impurity) *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and TA1538 PMRA #1755424/1755425	Negative
Bacterial Reverse Mutation Assay FMC 78162 (Bifenthrin impurity) *Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and TA1538 PMRA #1755426	Negative
Bacterial Reverse Mutation Assay FMC 78161 (Bifenthrin impurity)	Negative

	Study Results
Salmonella typhimurium TA98, TA100, TA1535, TA1537 and TA1538 PMRA #1755427	
CHO Mutation Assay FMC 102032 (Bifenthrin impurity) PMRA #1755419	Negative
Chromosomal Aberrations FMC 102032 (Bifenthrin impurity) CHO cells PMRA #1755420	Negative
Mouse Lymphoma Mutagenesis Assay FMC 78161 (Bifenthrin impurity) L5178Y TK+/- PMRA #1755422	Negative
Unscheduled DNA Synthesis FMC 102032 (bifenthrin impurity) PMRA #1755398	Negative
Micronucleus Cytogenetic Assay FMC 78161 (Bifenthrin impurity) ICR mouse bone marrow PMRA #1755412	Negative

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Bifenthrin

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or target MOE
Acute Dietary all populations	Acute oral neurotoxicity in rats	$BMDL_{20}$ = 2.6 mg/kg bw; based on decreased motor activity in the rat; in the co-critical rabbit developmental toxicity study based on head and forelimb twitching	300
	ARfD = 0.009 mg/kg bw		
Chronic Dietary all populations	Developmental toxicity study in rats; co-critical 1-year dog study	NOAEL = 1.0 mg/kg bw/day; based on maternal tremors in rat; in the co-critical dog study, tremors and delayed estrous	300
	ADI = 0.003 mg/kg bw/day		
Short-, Intermediate-Term Dermal all populations	21 day dermal toxicity in rats	NOAEL = 50 mg/kg bw/day; based on staggered gait, exaggerated hind-limb flexion, reduced tail flick latency	300
Short-, Intermediate-and Long-Term Inhalation all populations	Developmental toxicity study in rats	NOAEL = 1.0 mg/kg bw/day; based on maternal tremors	300
Cancer	Cancer risk for equivocal lung and liver tumors was addressed through the selected toxicology endpoints.		

[1] CAF (Composite assessment factor) refers to the total uncertainty and *Pest Control Products Act* factors for dietary and residential risk assessment; MOE refers to the target margin of exposure for occupational assessment

Table 5 Mixer/Loader/Applicator Dermal Exposure Estimates and MOEs

Application Method	Maximum Single Application Rate (kg a.i./ha) [1]	ATPD [2]	Dermal Unit Exposure Value (µg/kg a.i. handled) [3]	Dermal Exposure (mg/kg bw/day) [4]	Dermal MOE [5]
Groundboom (M/L/A)	0.337	20 ha/day	84.12	0.007087	7060
Airblast (M/L/A)	0.112	20 ha/day	3820.44	0.10697	467
Manually Pressurized Handwand	0.112	150 L/day	943.37	0.0003962	126000
Backpack	0.112	150 L/day	5445.85	0.002287	21900

[1] Supported rate

[2] ATPD for potatoes using groundboom equipment (farmer) is based on the largest area that can be planted in a single day because it is application at-plant only.

[3] Dermal unit exposure values for mixer/loader liquid open pour, groundboom applicator, low pressure handwand (M/L/A) and backpack (M/L/A) were taken from PHED. Airblast applicator dermal unit exposures were derived from AHETF. PHED M/L liquid open pour and AHETF airblast applicator unit exposure values were combined for total airblast M/L/A exposure.

[4] Dermal Exposure (mg/kg bw/day) = Application Rate (kg a.i./ha) × ATPD × Unit Exposure (µg/ kg a.i. handled) × Unit Conversion (mg/ 1000 µg) ÷ 80 kg bw. For sprayers, the ATPD was divided by the spray volume, 500 L/ha, provided by the applicant.

[5] Dermal MOE = NOAEL of 50 mg/kg bw/day ÷ Exposure; Target = 300

Table 6 Mixer/Loader/Applicator Inhalation and Combined Exposure Estimates and MOEs

Application Method	Maximum Single Application Rate (kg a.i./ha) [1]	ATPD [2]	Inhalation Unit Exposure Value (µg/kg a.i. handled) [3]	Inhalation Exposure (mg/kg bw/day) [4]	Inhalation MOE [5]	Combined MOE [6]
Groundboom (M/L/A)	0.337	20 ha/day	2.56	0.00021568	4640	2800
Airblast (M/L/A)	0.112	20 ha/day	10.68	0.00029904	3340	410
Manually Pressurized Handwand	0.112	150 L/day	45.2	0.000018984	52700	37200
Backpack	0.112	150 L/day	62.1	0.000026082	38300	13900

[1] Supported rate

[2] ATPD for potatoes using groundboom equipment (farmer) is based on the largest area that can be planted in a single day because it is application at-plant only.

[3] Inhalation unit exposure values for mixer/loader liquid open pour, groundboom applicator, low pressure handwand (M/L/A) and backpack (M/L/A) were taken from PHED. Airblast applicator inhalation unit exposures were derived from AHETF. PHED M/L liquid open pour and AHETF airblast applicator unit exposure values were combined for total airblast M/L/A exposure.

[4] Inhalation Exposure (mg/kg bw/day) = Application Rate (kg a.i./ha) × ATPD × Unit Exposure (µg/ kg a.i. handled) × Unit Conversion (mg/ 1000 µg) ÷ 80 kg bw. For sprayers, the ATPD was divided by the spray volume, 500 L/ha, provided by the applicant.

[5] Inhalation MOE = NOAEL of 1 mg/kg bw/day ÷ Exposure; Target = 300

[6] Combined MOE = 1 ÷ [(1/Dermal MOE) + (1/Inhalation MOE)]; Target = 300

Table 7 Postapplication Margin of Exposure on Raspberries

Re-entry activity	Peak DFR (µg/cm^2) [1]	Transfer coefficient (cm^2/hr)[2]	Dermal exposure (mg/kg bw/day) [3]	MOE [4]	REI [5]
Irrigation (hand-set)	0.2919	1750	0.0511	979	0
Tying/training (max foliage)	0.2919	1400	0.0409	1220	0
Hand harvesting	0.2128	1400	0.0298	1679	PHI = 3

[1] Calculated using the default 25% dislodgeable on the day of application and 10% dissipation per day

[2] Transfer coefficients obtained from ARTF data.

[3] Exposure = (Peak DFR [µg/cm^2] × TC [cm^2/hr] × 8 hours / (80 kg bw × 1000 µg/mg)

[4] Based on a NOAEL of 50 mg/kg bw/day, target MOE = 300 (see Table 3)

[5] Minimum REI is 12 hours to allow residues to dry but MOEs were calculated assuming 0 days for REI. A PHI of 3 days has been established for hand harvesting of raspberries

Table 8 Major groundwater and surface water model inputs for Level 1 assessment of bifenthrin

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Raspberries, potatoes
	Maximum allowable application rate per year (g a.i./ha)	224, 337
	Maximum rate each application (g a.i./ha)	112, 337
	Maximum number of applications per year	2, 1
	Minimum interval between applications (days)	30
	Method of application	airblast, in-furrow or T-band

Type of Input	Parameter	Value
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	stable
	Photolysis half-life in water (days)	41.7
	Adsorption K_{oc} (ml/g)	72490 (20th percentile of four K_{oc} values for "bifenthrin")
	Aerobic soil biotransformation half-life (days)	167 (90th percentile confidence bound on mean of four half-life values adjusted to 25°C)
	Aerobic aquatic biotransformation half-life (days)	276 (longest of two half-lives)
	Anaerobic aquatic biotransformation half-life (days)	0 (only value available)

Table 9 Level 1 estimated environmental concentrations of bifenthrin in potential drinking water sources

Crop	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)		
			Reservoir		
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Simulation Average[5]
Raspberries	NM	NM	1.5*	0.29	0.25
Potatoes	0	0	NM	NM	NM

[1] 90th percentile of daily average concentrations
[2] 90th percentile of yearly average concentrations
[3] 90th percentile of yearly peak concentrations
[4] 90th percentile of yearly average concentrations
[5] average of yearly average concentrations
* The limit of solubility in pH 7 buffered water is 1 µg a.i./L.
NM Not modelled

Table 10 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE – Apples, Cotton, Corn					PMRA # 1755373; 1755374; 1755375; 1755376; 1755377			
APPLES	PMRA # 1755373	1 application to surface of apple fruits with a pipet at a total rate of 24 g a.i./100 L (^{14}C-CP label)						
		1 or 3 applications on surface of leaves with a pipet at total rates of 24 g a.i./100 L (^{14}C-CP label) and 36 g a.i./100 L (^{14}C-PH label)						
	PMRA # 1755377	3 applications to surface of apple fruits using a pipet at a total rate of 144 g a.i./100 L (^{14}C-PH label)						
Radiolabel Position	**[Cyclopropyl (CP) Ring]**				**[Phenyl (PH) Ring]**			
Crop/Fraction	**Apple/Whole Fruit**				**Apple/Whole Fruit**			
Harvest Interval (days)	0	7	14	21	0	7	14	21
Overall TRR (mg/kg)	0.72	0.59	0.43	0.59	0.81	0.74	0.64	0.61
Major Metabolites (> 10% of TRR)	Bifenthrin				Bifenthrin			
Minor Metabolites (< 10% of TRR)	---				---			
Crop/Fraction	**Apple/Leaves**				**Apple/Leaves**			
Harvest Interval (days)	28				28			
Overall TRR (mg/kg)	Not reported				Not reported			
Major Metabolites (> 10% of TRR)	Bifenthrin				Bifenthrin			
Minor Metabolites (< 10% of TRR)	---				BP acid			

<table>
<tr><th colspan="5">NATURE OF THE RESIDUE – Apples, Cotton, Corn</th><th colspan="4">PMRA # 1755373; 1755374; 1755375; 1755376; 1755377</th></tr>
<tr><td rowspan="3">COTTON</td><td rowspan="2">PMRA # 1755375</td><td colspan="7">1 application to top surface of leaves at the 8-leaf stage with a microsyringe at total rates of 37.2 μg/leaf (^{14}C-CP label) and 25.2 μg/leaf (^{14}C-PH label)</td></tr>
<tr><td colspan="7">1 application to soil surface, at 8-leaf cotton growth stage, with a microsyringe at total rates of 2.5 kg a.i./ha (^{14}C-CP label) and 2.7 kg a.i./ha (^{14}C-PH label)
NOTE: As the test substances were applied to soil and only samples of soil (i.e. no samples of cotton) were taken for analysis, no results are reported herein for this treatment.</td></tr>
<tr><td>PMRA # 1755376</td><td colspan="7">1 application to cotton seeds (8 seeds treated) at a total rate of 1.3 μg a.i./seed (^{14}C-PH label)</td></tr>
<tr><td>Radiolabel Position</td><td colspan="4">[Cyclopropyl (CP) Ring]</td><td colspan="4">[Phenyl (PH) Ring]</td></tr>
<tr><td>Crop/Fraction</td><td colspan="4">---</td><td colspan="4">Cotton/Seeds</td></tr>
<tr><td>Harvest Interval (days)</td><td colspan="4">---</td><td colspan="2">0</td><td>14</td><td>28</td></tr>
<tr><td>Overall TRR (μCi)</td><td colspan="4">---</td><td colspan="2">0.37</td><td>0.31</td><td>0.22</td></tr>
<tr><td>Major Metabolites (> 10% of TRR)</td><td colspan="4">---</td><td colspan="4">Bifenthrin</td></tr>
<tr><td>Minor Metabolites (< 10% of TRR)</td><td colspan="4">---</td><td colspan="4">---</td></tr>
<tr><td>Crop/Fraction</td><td colspan="4">Cotton/Leaves</td><td colspan="4">Cotton/Leaves</td></tr>
<tr><td>Harvest Interval (days)</td><td>0</td><td>14</td><td>28</td><td>maturity</td><td>0</td><td>14</td><td>28</td><td>maturity</td></tr>
<tr><td>Overall TRR (mg/kg)</td><td>14.92</td><td>9.52</td><td>6.66</td><td>29.28</td><td>15.05</td><td>8.37</td><td>7.08</td><td>6.47</td></tr>
<tr><td>Major Metabolites (> 10% of TRR)</td><td colspan="4">Bifenthrin</td><td colspan="4">Bifenthrin</td></tr>
<tr><td>Minor Metabolites (< 10% of TRR)</td><td colspan="4">TFP acid</td><td colspan="4">BP acid, BP alcohol</td></tr>
<tr><td rowspan="3">CORN</td><td>Foliar treatment to leaves</td><td colspan="7">2 applications at the 2 feet stage and post tassel stage (RTI of 21 days) at total rates of 0.48 kg a.i./ha (^{14}C-CP label) and 0.43 kg a.i./ha (^{14}C-PH label)</td></tr>
<tr><td>Foliar treatment to leaves and husks</td><td colspan="7">1 application to husks 30 days prior to silage stage at total rates of 0.53 kg a.i./ha (^{14}C-CP label) and 0.48 kg a.i./ha (^{14}C-PH label) (<i>NOTE:</i> corn plants had received 2 foliar treatments)</td></tr>
<tr><td>Soil treatment</td><td colspan="7">3 applications at the 2 feet stage, post tassel stage and 30 days prior to silage stage (RTIs of 21 and 39 days) at total rates of 2.28 kg a.i./ha (^{14}C-CP label) and 2.26 kg a.i./ha (^{14}C-PH label)</td></tr>
<tr><td>Radiolabel Position</td><td colspan="4">[Cyclopropyl (CP) Ring]</td><td colspan="4">[Phenyl (PH) Ring]</td></tr>
<tr><td>Crop/Fraction</td><td colspan="4">Corn/Leaves</td><td colspan="4">Corn/Leaves</td></tr>
<tr><td>Type of Treatment</td><td colspan="4">Foliar to leaves</td><td colspan="4">Foliar to leaves</td></tr>
<tr><td>Harvest Interval (days)</td><td>0</td><td>7</td><td>14</td><td>30</td><td>0</td><td>7</td><td>14</td><td>30</td></tr>
<tr><td>Overall TRR (mg/kg) – treated samples</td><td>29.51</td><td>19.89</td><td>20.68</td><td>20.48</td><td>29.11</td><td>25.87</td><td>26.00</td><td>25.39</td></tr>
<tr><td>Overall TRR (mg/kg) – control samples</td><td>0.12</td><td>0.16</td><td>0.24</td><td>0.22</td><td>0.13</td><td>0.19</td><td>0.23</td><td>0.21</td></tr>
<tr><td>Major Metabolites (> 10% of TRR)</td><td colspan="4"><i>cis</i>-Bifenthrin</td><td colspan="4"><i>cis</i>-Bifenthrin</td></tr>
<tr><td>Minor Metabolites (< 10% of TRR)</td><td colspan="4"><i>trans</i>-Bifenthrin, 4′-OH-bifenthrin, TFP acid</td><td colspan="4"><i>trans</i>-Bifenthrin, 4′-OH-bifenthrin, BP acid, BP alcohol, BP aldehyde</td></tr>
<tr><td>Crop/Fraction</td><td colspan="4">Corn/Grain</td><td colspan="4">Corn/Grain</td></tr>
<tr><td>Type of Treatment</td><td colspan="2">Foliar to leaves</td><td colspan="2">Foliar to leaves and husks</td><td colspan="2">Foliar to leaves</td><td colspan="2">Foliar to leaves and husks</td></tr>
<tr><td>Harvest Interval (days)</td><td colspan="2">maturity</td><td colspan="2">maturity</td><td colspan="2">maturity</td><td colspan="2">maturity</td></tr>
<tr><td rowspan="2">Overall TRR (mg/kg)</td><td>control</td><td>treated</td><td>control</td><td>treated</td><td>control</td><td>treated</td><td>control</td><td>treated</td></tr>
<tr><td>0.053</td><td>0.057</td><td>0.053</td><td>0.063</td><td>0.056</td><td>0.056</td><td>0.056</td><td>0.069</td></tr>
<tr><td>Major Metabolites (> 10% of TRR)</td><td colspan="4">Not analysed</td><td colspan="4">Not analysed</td></tr>
<tr><td>Minor Metabolites (< 10% of TRR)</td><td colspan="4">Not analysed</td><td colspan="4">Not analysed</td></tr>
</table>

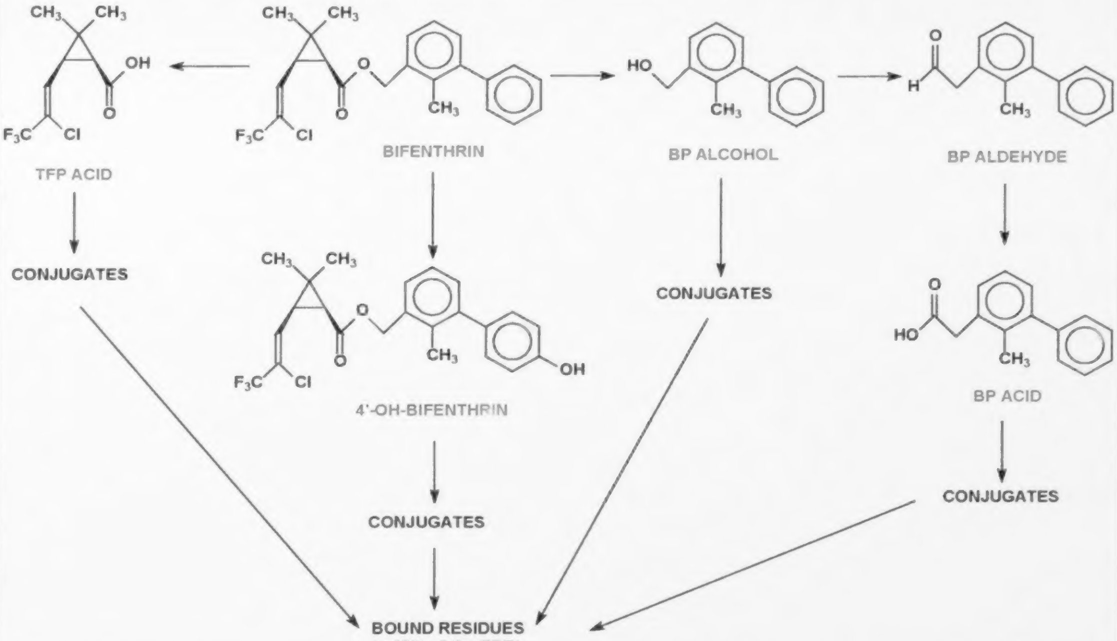
NATURE OF THE RESIDUE – Apples, Cotton, Corn			**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**	
Crop/Fraction	**Corn/Whole Plant**		**Corn/Whole Plant**	
Type of Treatment	Soil		Soil	
Harvest Interval	At silage stage		At silage stage	
Overall TRR (mg/kg)	control	treated	control	treated
	0.21	0.06	0.04	0.06
Major Metabolites (> 10% of TRR)	Not analysed		Not analysed	
Minor Metabolites (< 10% of TRR)	Not analysed		Not analysed	
Crop/Fraction	**Corn/Stalks and Leaves**		**Corn/Stalks and Leaves**	
Type of Treatment	Soil		Soil	
Harvest Interval	At maturity		At maturity	
Overall TRR (mg/kg)	control	treated	control	treated
	0.10	0.30	0.25	0.15
Major Metabolites (> 10% of TRR)	Not analysed		Not analysed	
Minor Metabolites (< 10% of TRR)	Not analysed		Not analysed	
Crop/Fraction	**Corn/Husks**		**Corn/Husks**	
Type of Treatment	Soil		Soil	
Harvest Interval	At maturity		At maturity	
Overall TRR (mg/kg)	control	treated	control	treated
	0.17	0.07	0.19	0.24
Major Metabolites (> 10% of TRR)	Not analysed		Not analysed	
Minor Metabolites (< 10% of TRR)	Not analysed		Not analysed	

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Lettuce, sugar beet and wheat					**PMRA # 1762331**		
Sandy loam soil was treated at a rate of 0.56 kg a.i./ha. Seeds of lettuce, sugar beet and wheat were sown at three plant-back intervals of 1, 2 and 4 months. Samples of wheat straw were analysed for identification/characterization of radioactive residues. Samples of sugar beet (roots, foliage), lettuce and wheat grain were not analysed further for identification/ characterization of radioactive residues although TRR levels in these matrices were above the trigger level of 0.01 ppm as per OECD Guidance Document on Overview of Residue Chemistry Studies (ENV/JM/MONO(2009)31) and OECD test guidelines 502. However, bifenthrin is not expected to be a predominant residue in/on sugar beet roots; sugar beet foliage, wheat grain and lettuce based on the results of the characterization/identification performed on wheat straw.							
Radiolabel Position		**[Cyclopropyl (CP) Ring]**			**[Phenyl (PH) Ring]**		
PBI (months)		1	2	4	1	2	4
Lettuce	**Overall TRR (mg/kg)**	**0.014**	**0.029**	**0.017**	**0.012**	**0.021**	**0.014**
Sugar beet foliage	**Overall TRR (mg/kg)**	**0.031**	**0.023**	**0.017**	**0.009**	**0.007**	**0.004**
Sugar beet roots	**Overall TRR (mg/kg)**	**0.021**	**0.019**	**0.008**	**0.009**	**0.008**	**0.005**
Wheat grain	**Overall TRR (mg/kg)**	**0.035**	**0.042**	**0.049**	**0.016**	**0.025**	**0.032**
Wheat straw	**Overall TRR (mg/kg)**	**0.247**	**0.247**	**0.312**	**0.094**	**0.160**	**0.193**
Major Metabolites (> 10% of TRR)		---			Bifenthrin (2-month PBI only)		
Minor Metabolites (< 10% of TRR)		4′-OH-bifenthrin, TFP acid			4′-OH-bifenthrin, BP acid, BP alcohol, BP aldehyde		

CONFINED ACCUMULATION IN ROTATIONAL CROPS – Wheat						**PMRA # 1762330**			
Sandy loam soil was treated at a rate of 0.56 kg a.i./ha. Seeds of wheat were sown at four plant-back intervals of 1, 4, 7 and 12 months. Samples of wheat straw and forage were analysed for identification/characterization of radioactive residues.									
Radiolabel Position		**[Cyclopropyl (CP) Ring]**				**[Phenyl (PH) Ring]**			
PBI (months)		1	4	7	12	1	4	7	12
Wheat forage	**Overall TRR (mg/kg)**	**0.283**	**0.116**	**0.089**	**0.034**	**0.192**	**0.054**	**0.041**	**0.010**
Major Metabolites (> 10% of TRR)		N/A	Bifenthrin (4-month PBI only); TFP acid		N/A	N/A	Bifenthrin (4-month PBI only); BP alcohol		N/A

NATURE OF THE RESIDUE – Apples, Cotton, Corn						**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**			
Minor Metabolites (< 10% of TRR)		N/A	Bifenthrin (7- and 12-month PBIs); 4′-OH-bifenthrin			N/A	Bifenthrin (7-month PBI only); 4′-OH-bifenthrin		N/A
Wheat straw	**Overall TRR (mg/kg)**	**0.371**	**0.335**	**0.151**	**0.175**	**0.326**	**0.100**	**0.047**	**0.077**
Major Metabolites (> 10% of TRR)		Bifenthrin (1-month PBI only); TFP acid				Bifenthrin (1- and 7-month PBIs)			
Minor Metabolites (< 10% of TRR)		Bifenthrin (4-, 7- and 12-month PBIs); 4′-OH-bifenthrin				Bifenthrin (4- and 12-month PBIs); 4′-OH-bifenthrin; BP alcohol			

Proposed Metabolic Scheme in Plants (Primary and Secondary Crops)



NATURE OF THE RESIDUE – Laying Hens	**PMRA # 1755380; 1755381; 1755382; 1755383**

Forty laying hens were dosed orally with [^{14}C-cyclopropyl (CP) ring]-bifenthrin and [^{14}C-phenyl (PH) ring]-bifenthrin at doses of 4 mg a.i./bird/day (corresponding to 30.8-31.5 ppm in feed) by gelatin capsule once daily for 10 consecutive days. Samples of excreta were collected on Study Days 8, 9 and 10. Samples of eggs were collected once daily in the morning. The hens were euthanized within 24 hours after administration of the final dose.

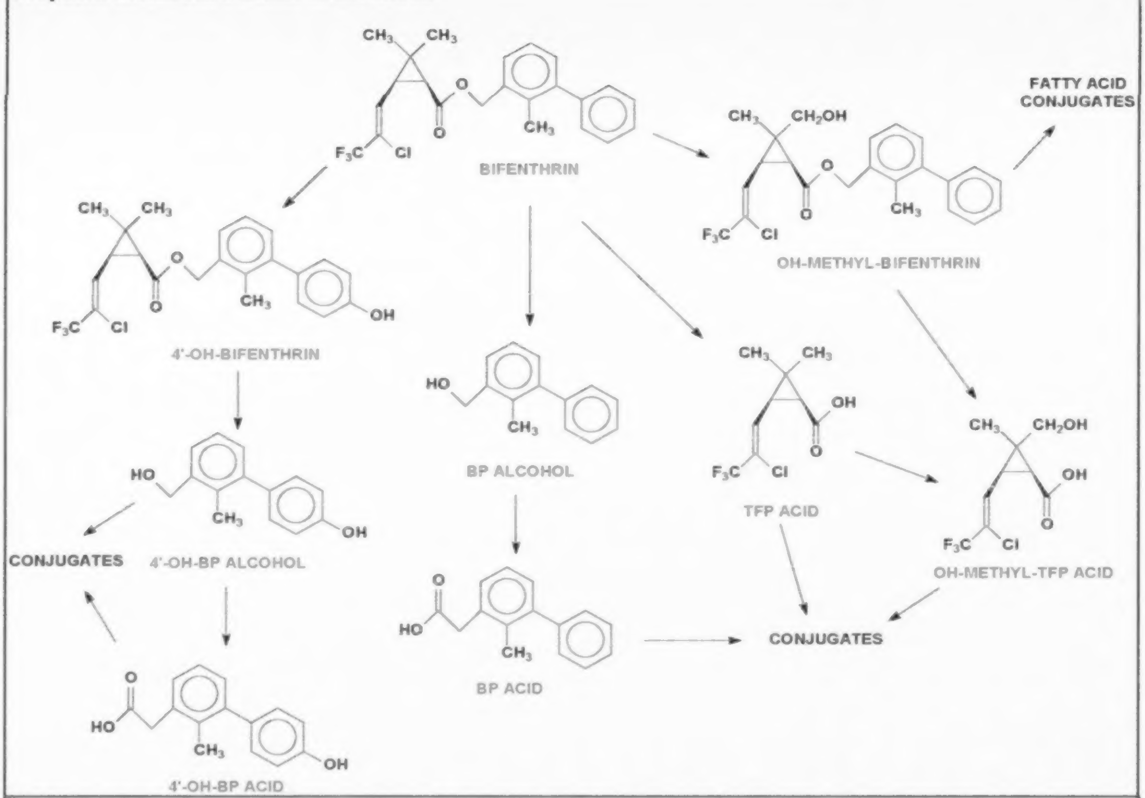
Matrices	**[^{14}C-Cyclopropyl (CP) Ring]**		**[^{14}C-Phenyl (PH) Ring]**	
	TRR (mg/kg)	**% of Administered Dose**	**TRR (mg/kg)**	**% of Administered Dose**
Excreta (Day 10)	55.0	Not reported	48.2	Not reported
Muscle (adductor)	0.144	Not reported	0.102	Not reported
Muscle (pectoral)	0.063	Not reported	0.035	Not reported
Fat (abdominal)	2.09	Not reported	2.17	Not reported
Liver	2.17	Not reported	1.36	Not reported
Egg Yolk (Day 10)	3.20	Not reported	3.28	Not reported
Egg White (Day 10)	0.042	Not reported	0.015	Not reported

NATURE OF THE RESIDUE – Apples, Cotton, Corn			**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**	
Metabolites identified	**Major Metabolites (>10% of the TRR)**		**Minor Metabolites (<10% of the TRR)**	
Radiolabel Position	**[^{14}C-CP Ring]**	**[^{14}C- PH Ring]**	**[^{14}C-CP Ring]**	**[^{14}C- PH Ring]**
Muscle (adductor)	Bifenthrin; combined OH-methyl bifenthrin and BP alcohol (PH label only)		4′-OH-bifenthrin; fatty acid conjugates of OH-methyl-bifenthrin; OH-methyl-bifenthrin	Fatty acid conjugates of OH-methyl-bifenthrin
Fat (abdominal)	Bifenthrin; fatty acid conjugates of OH-methyl-bifenthrin		OH-methyl-bifenthrin; TFP acid; OH-methyl-TFP acid	OH-methyl-bifenthrin; BP alcohol
Liver	Fatty acid conjugates of OH-methyl-bifenthrin; TFP acid (CP label only); OH-methyl-bifenthrin		OH-methyl-TFP acid; bifenthrin; TFP acid lactone	Bifenthrin; BP alcohol; 3′-4′-dimethoxy-BP *alcohol; 4′-methoxy-BP* alcohol; BP aldehyde; 3′-4′-dimethoxy-BP acid; 4′-methoxy-BP acid; BP acid
Egg Yolk (Day 10)	Bifenthrin; fatty acid conjugates of OH-methyl-bifenthrin		OH-methyl-bifenthrin; TFP acid	OH-methyl-bifenthrin; BP alcohol; 4′-OH-BP acid; 4′-OH-BP alcohol

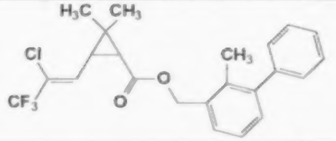
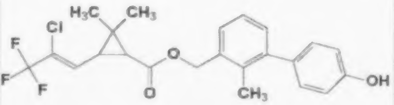
NATURE OF THE RESIDUE – Lactating Goats			**PMRA # 1755378; 1755379; 1755384; 1755385**	
Four lactating goats were dosed orally with [^{14}C-cyclopropyl (CP) ring]-bifenthrin and [^{14}C-phenyl (PH) ring]-bifenthrin at doses of 2.3 mg/kg bw (corresponding to 79 ppm in feed) by gelatin capsule twice daily for seven consecutive days. Samples of excreta were collected once daily and milk was collected twice daily. The goats were euthanized approximately 15 hours after administration of the final dose.				
Matrices	**[^{14}C-Cyclopropyl (CP) Ring]**		**[^{14}C-Phenyl (PH) Ring]**	
	TRR (mg/kg)	**% of Administered Dose**	**TRR (mg/kg)**	**% of Administered Dose**
Feces	Not reported	46	Not reported	48
Urine	Not reported	12	Not reported	12
Milk	Not reported	1.3	Not reported	1.2
Fat (omental; perirenal; subcutaneous)	0.86-2.1	0.97	0.97-2.3	0.97
Muscle (deltoid; flank; quadriceps)	0.25-0.38	0.42	0.24-0.29	0.38
Heart muscle	0.58	<0.2	0.48	<0.2
Kidney	0.39	<0.2	0.77	<0.2
Liver	2.1	0.24	3.6	0.46
Metabolites identified	**Major Metabolites (>10% of the TRRs)**		**Minor Metabolites (<10% of the TRRs)**	
Radiolabel Position	**[^{14}C-CP Ring]**	**[^{14}C- PH Ring]**	**[^{14}C-CP Ring]**	**[^{14}C- PH Ring]**
Milk	Bifenthrin		OH-methyl-bifenthrin	4′-OH-bifenthrin; OH-methyl-bifenthrin; BP acid; BP alcohol
Fat (perirenal)	Bifenthrin		4′-OH-bifenthrin; OH-methyl-bifenthrin; TFP acid	4′-OH-bifenthrin; OH-methyl-bifenthrin; BP alcohol
Muscle (quadriceps)	Bifenthrin		OH-methyl-bifenthrin	4′-OH-bifenthrin; OH-methyl-bifenthrin; BP alcohol
Heart muscle	Bifenthrin		4′-OH-bifenthrin; OH-methyl-bifenthrin; TFP acid	4′-OH-bifenthrin; OH-methyl-bifenthrin; BP alcohol

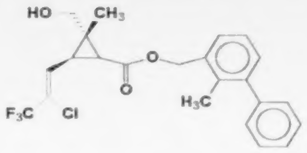
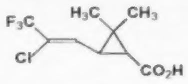
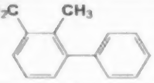
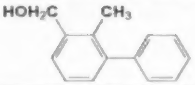
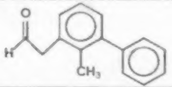
NATURE OF THE RESIDUE – Apples, Cotton, Corn			**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**	
Kidney	Bifenthrin	Bifenthrin; BP acid	4′-OH-bifenthrin; OH-methyl-bifenthrin; TFP acid; OH-methyl-TFP acid	BP alcohol; 4′-OH-BP alcohol
Liver			OH-methyl-bifenthrin; TFP acid; OH-methyl-TFP acid	OH-methyl-bifenthrin; BP alcohol

Proposed Metabolic Scheme in Livestock


BIFENTHRIN
FATTY ACID CONJUGATES
OH-METHYL-BIFENTHRIN
4′-OH-BIFENTHRIN
BP ALCOHOL
TFP ACID
OH-METHYL-TFP ACID
CONJUGATES
4′-OH-BP ALCOHOL
BP ACID
CONJUGATES
4′-OH-BP ACID

List of Metabolites Identified in Plant and Livestock Metabolism Studies

Common name (Company code)	Chemical name	Chemical structure	Found in metabolism studies
Bifenthrin (FMC 54800)	[2-methyl-(1,1′-biphenyl)-3-yl]-methyl-cis,trans-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl) cyclopropanecarboxylate		Apple; cotton; corn; wheat; hen; goat
4′-OH-bifenthrin (FMC 78128)	3-(4′-hydroxyphenyl)-2-methylbenzyl(±)*cis*-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropane-carboxylate		Corn; wheat; hen; goat

NATURE OF THE RESIDUE – Apples, Cotton, Corn		**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**	
Hydroxymethyl-bifenthrin (OH-methyl-bifenthrin; FMC 108561)	2-Methyl-[1,1`biphenyl]-3-yl)-methyl-*cis*-3-(2-chloro- 3,3,3-trifluoro-1-propenyl) *trans*-2-hydroxymethyl2-methylcyclopropane-carboxylate		Hen; goat
TFP acid (FMC 53997)	*cis, trans*-3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-cyclopropanecarboxylic acid		Cotton; corn; wheat; hen; goat
Biphenyl acid (BP acid; FMC 65328)	2-methyl-3-phenylbenzoic acid		Cotton; corn; wheat; hen; goat
Biphenyl alcohol (BP alcohol; FMC 56789)	2-methyl-3-phenylbenzyl alcohol		Cotton; corn; wheat; hen; goat
Biphenyl aldehyde (BP aldehyde)	2-methyl-3-phenylbenzylaldehyde		corn

FREEZER STORAGE STABILITY – Plant Matrices	**PMRA # 1762217; 1762218; 1762212; 1762211; 1762215; 1762216; 1762219; 1762220; 1762221**	
Samples were stored at -38°C to 0°C. The data can be extended to crop field trials and processing studies to cover the maximum storage intervals observed.		
Commodity Categories	**Representative Commodities**	**Demonstrated Duration of Stability**
High water content	Head lettuce	183 days [6 months]
	Apple fruits	1490 days [49 months]
	Field corn silage, stover	1490 days [49 months]
	Bananas	730 days [24 months]
High oil content	Cottonseed	730 days [24 months]
	Pecan	1095 days [36 months]
High protein content	Dried shelled peas	440 days [14.5 months]
High starch content	Potato tubers	1095 days [36 months]
	Field corn grain	1034 days [34 months]
High acid content	Orange	548 days [18 months]
Processed fractions	Orange (dried pulp, juice, oil)	548 days [18 months]
	Field corn (flour, meal, starch, refined oil)	365 days [12 months]

FREEZER STORAGE STABILITY – Animal Matrices	**PMRA # 1762220; 1762221**	
Samples were stored in freezer at -18°C. The demonstrated duration of stability covers the maximum storage interval observed in the livestock feeding studies.		
Species	**Commodity**	**Demonstrated Duration of Stability**
Cattle	Fat	36 months
	Liver	36 months
	Muscle	36 months
	Milk	36 months
Poultry	Eggs	36 months

CROP FIELD TRIALS – Potatoes and Raspberries	**PMRA # 1762335; 1762236**

DOMESTIC REGISTRATION AND IMPORTED COMMODITIES

Potatoes and raspberries are petitioned for domestic registration. Tuberous and corm vegetables (CSG 1C) and caneberry (CSG 13-07A) are petitioned for importation to Canada.

Crops:	**Potatoes**		**Raspberries and Blackberries**	
Number of Trials:	12		4 and 1	
Trial Locations:	Conducted in various NAFTA growing regions			
Formulation Type:	2 lb a.i./gal Emulsifiable Concentrate (2EC) and 1.15 lb a.i. Granular (1.15G)		10% a.i. by weight Wettable Powder (10WP) or Water-Soluble Bag (WSB)	
Application Type:	First appl.: in-furrow at planting (2EC or 1.15 G) Second/third appl.: broadcast foliar (2EC)		Two foliar directed spray applications at pre-bloom and during maturation of berries	
Adjuvant Use:	None		None	
Residue Decline Trend:	None		No residue-decline samples harvested.	
X-fold Approved GAP	CDN: 1.8	US: 1.0	CDN: 1.0	US: 1.0

Commodity	**Total App. Rate [kg a.i./ha]**	**PHI (days)**	**Bifenthrin Residue Levels (ppm)**							
			n	**Min.**	**Max.**	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Potatoes	0.56-0.61 (1.15 G and 2EC)	21	24	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0
	0.56-0.61 (2EC)	21	24	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0
Raspberries	0.224 (WSP or 10WP)	3	8	0.08	0.54	0.08	0.44	0.35	0.32	0.17
Blackberries	0.224 (WSB)	2	2	0.68	0.80	0.74	0.74	0.74	NA	NA

CROP FIELD TRIALS – Carrot; radish; garden beet; head lettuce; spinach; celery	**PMRA # 1762237; 1762248; 1762240; 1762295; 1762243; 1762250; 1762270; 1828919; 1762238; 1762265**

IMPORTED COMMODITIES

CG/CSG	**1A/B**	**1A/B**	**1A/B**	**4-13A**	**4-13A**	**22B**
Crops:	**Carrot**	**Radish**	**Garden Beet**	**Head Lettuce**	**Spinach**	**Celery**
Number of Trials:	10	6	6	10	8	12
Trial Locations:	Trials were conducted in appropriate NAFTA Growing Regions.					
Formulation Type:	2 lb a.i./gal Emulsifiable Concentrate (2EC); 1.15 lb a.i. Granular (1.15G); 10% a.i. by weight Wettable Powder (10WP)					
Application Type:	3 or 4 foliar (directed or broadcast) applications to carrot and garden beet; 1 in-furrow at planting + 2 foliar (directed or broadcast) applications to radish; foliar (directed or broadcast) applications to head lettuce and celery (5-6 appl.); foliar ground spray to spinach (1 or 4 appl.)					
Adjuvant Use:	None					
Residue Decline Trend:	No residue decline was observed in carrot roots and celery. Residue decline profile observed for bifenthrin residues in/on head lettuce and spinach.					
X-fold Registered GAP	1.0	0.4	1.0	1.0	1.0	1.0

Crop	**Total App. Rate [kg a.i./ha]**	**PHI (days)**	**Bifenthrin Residue Levels (ppm)**							
			n	**Min.**	**Max.**	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Carrot roots	0.550-0.575	20-22	20	< 0.05	< 0.05	0.05	0.05	0.05	0.05	0
Radish roots	0.221-0.241	6-8	12	< 0.05	0.07	0.05	0.06	0.05	0.05	0.01
Radish tops			12	0.56	2.25	0.63	2.25	1.65	1.51	0.58
Garden beet	0.448-0.460	1	12	< 0.05	0.28	0.05	0.28	0.06	0.11	0.09

NATURE OF THE RESIDUE – Apples, Cotton, Corn							**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**			
roots										
Garden beet tops			12	4.80	12.2	5.0	11.9	6.35	7.29	2.55
Head lettuce	0.56-0.67	6-8	8	<0.05	1.91	0.05	1.76	0.51	0.67	0.59
Spinach	0.448-0.467	36-41	14	<0.05	0.16	0.05	0.15	0.05	0.07	0.04
Celery	0.497-0.566	6-8	32	0.06	1.26	0.10	1.16	0.52	0.57	0.35

CROP FIELD TRIALS – Mustard greens; broccoli; cauliflower; cabbage; soybean; edible-podded pea and bean; succulent shelled pea and bean; dried shelled pea and bean; tomato			**PMRA # 1762262; 1762263; 1762264; 1762242; 1762317; 1762235; 1762245; 1762234; 1762271; 1762225**			
IMPORTED COMMODITIES						
CG/CSG	**4-13B**	**5-13**	**6**	**6A/B**	**6C**	**8-09A**
Crops:	***Brassica* Leafy Greens**	***Brassica* Head and Stem Vegetables**	**Soybeans**	**Edible-Podded and Succulent Shelled Pea and Bean**	**Dried Shelled Pea and Bean**	**Tomatoes**
Number of Trials:	4 (broccoli) 7 (cabbage) 4 (cauliflower)	8 (mustard greens)	15	6-7 for each commodity	6 (pea) 9 (bean)	16
Trial Locations:	Trials were conducted in appropriate NAFTA Growing Regions.					
Formulation Type:	2 lb a.i./gal Emulsifiable Concentrate (2EC)					
Application Type:	Foliar (directed or broadcast) spray to *Brassica* head and stem vegetables (5-11 appl. to broccoli; cabbage and cauliflower); to *Brassica* leafy vegetables (4 appl. to mustard greens); to legume vegetables (2-3 appl.); and tomatoes (4 appl.)					
Adjuvant Use:	None					
Residue Decline Trend:	No residue decline was observed in cabbage, soybeans, dried shelled peas and beans, and tomatoes.					
X-fold Registered GAP	0.8-1.1	1.0	1.0	1.0	1.0	0.8-1.0

Crop	**Total App. Rate [kg a.i./ha]**	**PHI (days)**	**Bifenthrin Residue Levels (ppm)**							
			n	**Min.**	**Max.**	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Mustard greens	0.445-0.479	6-7	16	0.05	2.05	0.07	2.01	1.04	1.08	0.71
Broccoli	0.560	6-7	10	< 0.05	0.56	0.06	0.44	0.16	0.19	0.16
Cauliflower	0.560	6-8	10	< 0.05	0.19	0.05	0.18	0.07	0.10	0.05
Cabbage	0.560	6-7	5	0.44	3.09	0.57	3.09	1.45	1.44	1.03
Soybean	0.334-0.336	17-18	28	< 0.05	0.18	0.05	0.18	0.05	0.06	0.03
Edible-podded pea	0.224	3	11	0.16	0.50	0.17	0.49	0.19	0.27	0.14
Edible-podded bean	0.224	2-4	12	< 0.05	0.15	0.05	0.14	0.05	0.08	0.04
Succulent shelled pea	0.224	3	11	< 0.05	< 0.05	0.05	0.05	0.05	0.05	0
Succulent shelled bean	0.223-0.225	2-4	14	< 0.05	< 0.05	0.05	0.05	0.05	0.05	0
Dried shelled pea	0.224	14-15	12	< 0.05	< 0.05	0.05	0.05	0.05	0.05	0
Dried shelled bean	0.336	13-15	18	< 0.05	0.10	0.05	0.10	0.05	0.06	0.02
Tomato	0.347-0.364	0	4	<0.05	0.10	0.07	0.09	0.08	0.08	0.02
		3	4	<0.05	0.11	0.06	0.10	0.08	0.08	0.03

NATURE OF THE RESIDUE – Apples, Cotton, Corn									**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**	
		4	4	0.06	0.09	0.07	0.08	0.07	0.07	0.02
		5	20	<0.05	0.09	0.05	0.09	0.06	0.06	0.01
		6	4	<0.05	<0.05	0.05	<0.05	0.05	0.05	0
		7	4	<0.05	0.10	0.07	0.08	0.07	0.07	0.02
		9	4	<0.05	0.05	0.05	0.05	0.05	0.05	0

CROP FIELD TRIALS – Bell pepper; nonbell pepper; eggplant; cantaloupe; cucumber; summer squash; pear; mayhaw; tea			**PMRA # 1762246; 1762247; 1762266; 1762228; 1762229; 1762232; 1762285; 1762286; 1762311; 1762245; 1762324 1762244; 1828908; 1828909; 1828910; 1828911; 1828912; 1828915**		
			IMPORTED COMMODITIES		
CG/CSG	**8-09B/C**	**9**	**11-09**	**11-09**	**N/A**
Crops:	**Pepper (Bell; Nonbell); Eggplant**	**Cucurbit Vegetables**	**Pear**	**Mayhaw**	**Tea**
Number of Trials:	5 (bell pepper) 7 (nonbell pepper) 3 (eggplant)	7 (cantaloupe) 9 (cucumber) 9 (summer squash)	3 (at US GAP) (23 not at US GAP)	3	3
Trial Locations:	Trials were conducted in appropriate NAFTA Growing Regions.				Trials conducted in India (Southern and North-Eastern regions)
Formulation Type:	2 lb a.i./gal Emulsifiable Concentrate (2EC); 10% a.i. by weight Wettable Powder (10WP)				
Application Type:	Foliar (directed or broadcast) sprays to peppers, eggplants and mayhaw (2 appl.); foliar (directed or broadcast) sprays to and pears (1-5 appl.); ground or aerial broadcast spray to cucurbit vegetables (3 appl.); spray to tea plants (1 appl.)				
Adjuvant Use:	None				
Residue Decline Trend:	No residue decline profile was observed in cucurbit vegetables. A residue decline was observed in pears.				
X-fold Registered GAP	0.75-1.0	1.0	0.4-2.0	1.0	0.38 (Japan); 1.0 (Korea); 1.1 (China, Taiwan)

Crop	**Total App. Rate [kg a.i./ha]**	**PHI (days)**	**Bifenthrin Residue Levels (ppm)**							
			n	**Min.**	**Max.**	**LAFT**	**HAFT**	**Median**	**Mean**	**SD**
Bell pepper	0.223-0.227	6-7	10	<0.055	0.24	0.06	0.17	0.09	0.10	0.06
Nonbell pepper	0.168-0.227	6-7	14	<0.05	0.31	0.05	0.29	0.11	0.14	0.08
Eggplant	0.224	7	6	<0.05	<0.05	0.05	0.05	0.05	0.05	0
Cantaloupe	0.336	3	14	<0.10	0.35	0.10	0.32	0.10	0.14	0.08
Cucumber	0.336	3	18	<0.10	0.24	0.10	0.20	0.10	0.12	0.04
Summer squash	0.336	3	20	<0.10	0.18	0.10	0.15	0.10	0.10	0.02
Pear	0.560-0.571 (10WP; HVS)	14	6	0.10	0.38	0.12	0.33	0.18	0.21	0.10
	0.560-0.571 (10WP; LVS)	14	6	0.12	0.43	0.21	0.35	0.25	0.28	0.13
	0.673-1.12 (10WP)	14	20	0.07	0.039	0.08	0.37	0.26	0.25	0.09
	0.673-1.12 (2EC)	14	6	0.07	0.56	0.09	0.55	0.20	0.28	0.21
Mayhaw	0.224-0.227	28-29	6	0.24	0.78	0.26	0.75	0.39	0.47	0.23
Tea (fresh)	0.060	7	9	0.66	5.05	0.81	4.87	4.81	3.51	2.03
Tea (black)			9	0.39	5.85	0.40	5.71	4.85	3.66	2.47

RESIDUE DATA IN ROTATIONAL CROPS – Winter Wheat	**PMRA # 2409361**
Seven field trials for bifenthrin on winter wheat as a rotational crop were conducted in the United States encompassing NAFTA Growing Regions 4 [1 trial], 5 [4 trials] and 8 [2 trials] during the 1999-2000 growing season. Wheat was planted as a rotational crop 30-32 days after the last application of bifenthrin to primary crops (i.e. cotton, field corn, sweet corn). Samples of wheat forage, hay, straw and grain were collected at maturity.	

NATURE OF THE RESIDUE – Apples, Cotton, Corn	**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**

Commodity	Total Application Rate (kg a.i./ha)	PBI (days)	Residue Levels (ppm)							
			n	Min. #	Max. #	LAFT *	HAFT *	Median *	Mean *	SD *
Wheat forage	0.559-0.560	30-32	14	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0
Wheat hay			14	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0
Wheat straw			14	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0
Wheat grain			14	< 0.05	< 0.05	< 0.05	< 0.05	0.05	0.05	0

Values based on total number of samples.

* Values based on per-trial averages. LAFT = Lowest Average Field Trial. HAFT = Highest Average Field Trial. SD = Standard Deviation. For computation of the LAFT, HAFT, median, mean and standard deviation, values < LOQ are assumed to be at the LOQ.

n = number of field trials.

Based on the results of the field accumulation study, a plant-back interval of 30 days is required for wheat. All the other crops not appearing on the label will have a plant-back interval of 365 days.

PROCESSED FOOD AND FEED – Potatoes; Soybeans; Tomatoes; Pears	**PMRA # 1762320; 1762335; 1762317; 1762225; 1762340**

Processing studies were conducted using samples from crop field trials conducted in NAFTA growing regions. The at plant band application (i.e. first application) to potatoes was made with a granular (G) formulation. The ground or broadcast foliar spray applications were made with an emulsifiable concentrate (2EC) or a wettable powder (10WP) formulation. As per DIR98-02, Section 10.6.3, the residues in processed potato and soybean fractions are corrected for the degree of exaggeration: P*f* = [Residues in processed fraction ÷ Degree of exaggeration] ÷ LOQ in RAC.

RAC	Processed Commodity	Total Rate (kg a.i./ha)	X-Fold GAP	PHI (days)	Average Residues (ppm)	Processing Factor (P*f*)	RAC HAFT	Anticipated Residue (ppm)
Potato	Tuber (RAC)	1.68	5	21	< 0.05	---	< 0.05	---
	Granule				< 0.05	1		0.05
	Chip				< 0.05	1		0.05
	Wet peel				< 0.05	1		0.05
	Dry peel				0.094	0.4		0.02
Soybean	RAC	0.78	2.3	18	< 0.05	---	0.18	---
	Meal				< 0.05	1		0.18
	Hulls				0.07	0.6		0.11
	Refined oil				< 0.05	1		0.18
	AGFs				9.51	83		15
Tomato	RAC	0.361	0.8 (2EC) or 1 (WSB)	5	0.075	---	0.10 (at 3-day PHI)	---
	Purée				< 0.05	0.67		0.07
	Paste				< 0.05	0.67		0.07
Pear	RAC	0.560	1	14	0.633	---	0.35	---
	Wet pomace (peeled)				1.776	2.81		0.97
	Wet pomace (ground)				9.223	14.6		5.0
	Canned pear (peeled)				< 0.01	0.016		0.005
	Purée (peeled)				< 0.01	0.016		0.005
	Purée (ground)				0.014	0.022		0.008
	Nectar (peeled)				< 0.01	0.016		0.005
	Nectar (ground)				0.011	0.017		0.006

LIVESTOCK FEEDING – Dairy cattle	**PMRA # 1762350; 1762353; 1762355; 1762356; 1792357; 1762346; 1762351**

Lactating dairy cows were administered orally twice daily for 28 consecutive days with gelatin capsules containing bifenthrin at dose levels of 5 ppm (45-fold), 15 ppm (136-fold), and 50 ppm (455-fold) of the estimated dietary burden for dairy cattle. Only the values from the feeding level closest to the estimated dietary burden are reported. Some cattle matrices were also analysed for metabolites of bifenthrin. As these metabolites are not part of the residue definition, the results are not reported herein.

NATURE OF THE RESIDUE – Apples, Cotton, Corn				**PMRA # 1755373; 1755374; 1755375; 1755376; 1755377**		
Commodity	**Feeding Level (ppm)**	**Bifenthrin Residues (ppm)**		**Dietary Burden (DB) (ppm)**	**Anticipated Bifenthrin Residues (ppm)**	
		mean	**max**	**Beef cattle**	**mean**	**max**
Muscle (adductor)	5	< 0.10	< 0.10	0.11	0.0022	0.0022
Muscle (pectoral)		< 0.10	< 0.10		0.0022	0.0022
Muscle (cardial)		< 0.10	< 0.10		0.0022	0.0022
Liver		< 0.10	< 0.10		0.0022	0.0022
Kidney		< 0.10	< 0.10		0.0022	0.0022
Fat (subcutaneous)		0.50	0.77		0.0109	0.0169
Fat (peritoneal)		1.22	1.82		0.027	0.040
Whole milk		0.08	0.12		0.0018	0.0026
Milk fat		0.53	0.62		0.012	0.014
LIVESTOCK FEEDING – Laying hen				**PMRA # 1762348; 1762349; 1762354; 1762347; 1762352**		
Laying hens were administered orally once daily for 28 consecutive days with gelatin capsules containing bifenthrin at dose levels of 1.96 ppb (0.05-fold), 21.0 ppb (0.5-fold) and 216 ppb (5.4-fold) of the estimated dietary burden for laying hens. Only the values from the feeding level closest to the estimated dietary burden are reported. Some poultry matrices were also analysed for metabolites of bifenthrin. As these metabolites are not part of the residue definition, the results are not reported herein.						
Commodity	**Feeding Level (ppm)**	**Bifenthrin Residues (ppm)**		**Dietary Burden (DB) (ppm)**	**Anticipated Bifenthrin Residues (ppm)**	
		mean	**max**	**Laying hen**	**mean**	**max**
Muscle (thigh)	0.216	< 0.02	< 0.02	0.04	< 0.02	< 0.02
Muscle (breast)		< 0.02	< 0.02		< 0.02	< 0.02
Fat (subcutaneous)		< 0.05	< 0.05		< 0.05	< 0.05
Liver		< 0.05	< 0.05		< 0.05	< 0.05
Eggs (Day 28)		< 0.01	< 0.01		< 0.01	< 0.01

Table 11 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT **Primary crops (apples; cotton; corn)** **Rotational crops (wheat)**		Bifenthrin	
RESIDUE DEFINITION FOR RISK ASSESSMENT **Primary crops (apples; cotton; corn)** **Rotational crops (wheat)**		Bifenthrin	
METABOLIC PROFILE IN DIVERSE CROPS		Similar in apples, cotton, corn and wheat.	
ANIMAL STUDIES			
ANIMALS		**Ruminant and Poultry**	
RESIDUE DEFINITION FOR ENFORCEMENT		Bifenthrin	
RESIDUE DEFINITION FOR RISK ASSESSMENT		Bifenthrin	
METABOLIC PROFILE IN ANIMALS **(goat, hen, rat)**		The profile in similar in the investigated animals.	
FAT SOLUBLE RESIDUE		Yes	
DIETARY RISK FROM FOOD AND WATER			
Refined chronic (cancer and non-cancer) dietary exposure analysis **ADI = 0.003 mg/kg bw/day** **Estimated chronic drinking water concentration = 0.29 µg a.i./L**	**POPULATION**	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Alone	**Food and Water**
	All infants < 1 year	18.1	18.8
	Children 1–2 years	33.6	33.9
	Children 3 to 5 years	28.9	29.2
	Children 6–12 years	18.9	19.1
	Youth 13–19 years	13.0	13.2

PLANT STUDIES			
	Adults 20–49 years	14.9	15.0
	Adults 50+ years	15.2	15.4
	Females 13-49 years	14.1	14.3
	Total population	16.5	16.7
Refined acute dietary exposure analysis, 95th percentile **ARfD = 0.009 mg/kg bw** **Estimated acute drinking water concentration = 1.5 µg a.i./L** **Monitoring data (highest detection) = 5.2 µg a.i./L *(Note: this value was used in estimated risk)***	**POPULATION**	**ESTIMATED RISK % of ACUTE REFERENCE DOSE (ARfD)**	
		Food Alone	**Food and Water**
	All infants < 1 year	41.9	47.1
	Children 1–2 years	71.8	75.2
	Children 3 to 5 years	59.5	61.4
	Children 6–12 years	38.6	39.6
	Youth 13–19 years	27.9	29.0
	Adults 20–49 years	28.2	29.6
	Adults 50+ years	27.7	28.9
	Females 13-49 years	25.7	27.0
	Total population	33.8	35.4

Table 12 Fate and Behaviour in the Environment

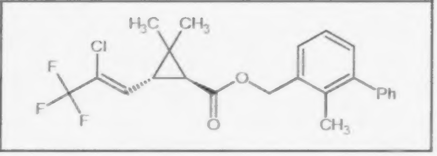
Study	Test substance	Value	Comments	Reference
Abiotic transformation				
Hydrolysis (25°C)	Bifenthrin	Stable	Not expected to be a route of dissipation	1924822
Phototransformation on soil (20°C)	Bifenthrin	Based on 12 hours of daylight DT_{50}: 115 d, DT_{90}: 382 d	Not expected to be a route of dissipation (half-life >7 days)	1755325
Phototransformation in water (25°C)	Bifenthrin	Based on 12 hours of daylight DT_{50}: 31.6 to 51.8 d, DT_{90}: 105-173 d	Not expected to be a route of dissipation (half-life >7 days)	1924824
Phototransformation in air	The vapour pressure and Henry's law constant of bifenthrin suggest that bifenthrin has low potential to volatilize from water and moist soil. The Atkinson method predicted that any bifenthrin released to the air would have an atmospheric half-life less than one day. However, given the adsorption properties of bifenthrin, indirect photo oxidation may not be a major route of dissipation in air.			
Biotransformation				
Biotransformation in aerobic soil (20°C)	Bifenthrin	**Bifenthrin (combined labels)**		1755314 1755315 1755318 1755319 1755321 1755322
		Hagertown silt clay DT_{50} = 112 d, DT_{90} = 371 d	Persistent	
		Cosad sandy loam DT_{50} = 89.4 d, DT_{90} = 1399 d	Moderately persistent	
		Dunkirk silt loam DT_{50} = 203 d, DT_{90} = 674 d	Persistent	
		Georgetown silt loam DT_{50} = 78.7 d, DT_{90} = 261 d	Moderately persistent	
		Arlington DT_{50} for *R-cis*: 277days DT_{50} for *S-cis*: 330 days	Persistent	Qin *et al* 2006
Biotransformation in anaerobic soil	Bifenthrin	DT_{50} > 1000	Persistent	1924829
		Arlington DT_{50} for *R-cis*: 770 days DT_{50} for *S-cis*: 495 days	Persistent	Qin *et al* 2006

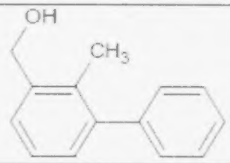
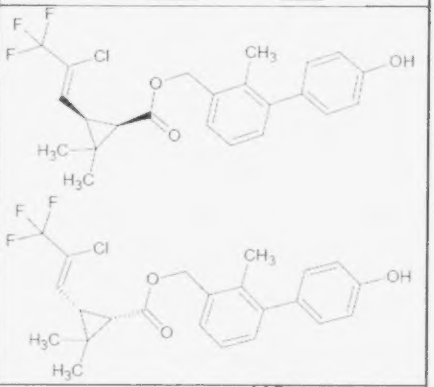
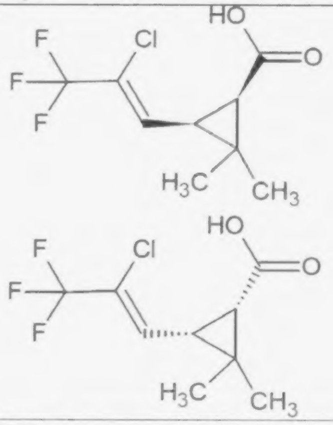
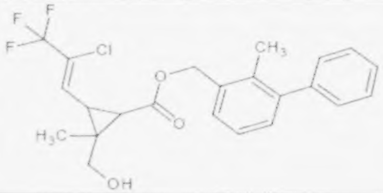
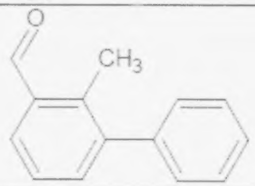
Study	**Test substance**	**Value**	**Comments**	**Reference**
Biotransformation in aerobic water-sediment systems (20°C)	Bifenthrin	Calwich lake Water DT_{50} = 1.86 d, DT_{90} = 6.16 d Whole system DT_{50} = 276 d, DT_{90} = 918 d	Persistent	1755309
		Swiss lake Water DT_{50} = 1.7 d, DT_{90} = 5.66 d Whole system DT_{50} = 92.9 d, DT_{90} = 308 d	Moderately persistent	
Biotransformation in anaerobic water-sediment systems	Study not required as the anaerobic (flooded) soil study addressed this requirement.			1755308
Mobility				
Adsorption / desorption in soil	Bifenthrin	Leon fine sand K_d = 2005 mL/g, K_{OC} = 115245 mL/g	Immobile	1755306 1924831
		Cosad sandy loam K_d = 2685 mL/g, K_{OC} = 154299 mL/g		
		Dunkirk silt loam K_d = 1800 mL/g, K_{OC} = 103474 mL/g		
		Hagerstown clay loam K_d = 453 mL/g, K_{OC} = 26013 mL/g		
	TFP acid	M sandy loam K_d = 118 mL/g, K_{OC} = 411 mL/g	Moderately mobile	1755305
		J1 loamy clay K_d = 0.742 mL/g, K_{OC} = 15.6 mL/g	Very highly mobile	
		A1 sand K_d = 5.49 mL/g, K_{OC} = 499 mL/g	Moderately mobile	
		E3 silty loam K_d = 7.94 mL/g, K_{OC} = 241 mL/g	Moderately mobile	
		Horn sandy loam K_d = 0.573 mL/g, K_{OC} = 24.6 mL/g	Very highly mobile	
	4'-OH bifenthrin	K_{OC}: 3,043-397,253 mL/g	Low mobility to immobile	2533219
Volatilization from soil	Bifenthrin	< 2% TAR of bifenthrin detected in volatile traps.	No classification	1755299 1755300
Bioconcentration/Bioaccumulation				
Bioconcentration in fish	Bifenthrin	Carp: BCF_{SS}: 709 – 1170 BCF_{K}: 815-1200 $BCF_{K,G}$: 809-1191 $BCF_{K,G,L}$: 1265 - 1861		1755224
		Bluegill sunfish: BCF_{SS}: 1584-1649 BCF_{SS}: 5% lipid normalized: 2507 - 2820 BCF_{K}: 2117-2147 $BCF_{K,G}$: 2251-2325 $BCF_{K,G,L}$: 3400-3511		1755215
		Bluegill sunfish: Based on measured bifenthrin in water: BCF_{SS}: 6090 BCF_{K}: 12850		1755218 1755216

Study	Test substance	Value	Comments	Reference
		Based on nominal bifenthrin in water: BCF_{SS}: 2107 BCF_K: 5250		
		Fathead minnow: (not corrected for growth dilution or lipid content) F_0 adult BCF_{SS}: 21,000-30,000		1755227
Bioconcentration in *D. magna*	Bifenthrin	$BCF_K = 4750$ $BCF_{K,G} = 6273$		2533225
Dietary biomagnification in *D. magna*	Bifenthrin	$BMF_{SS} = 0.11$ $BMF_K = 0.11$ $BMF_{K,G}$: 0.11 $BMF_{K,G,L}$: 0.11	The study indicates that bifenthrin did not biomagnify in this study as the reported BMFs are <1.0.	2533226
Dietary biomagnification in bluegill sunfish	Bifenthrin	Bluegill sunfish: $BMF_K = 0.08$ $BMF_{K,G} = 0.13$ $BMF_{K,G,L} = 0.28$	The study indicates that bifenthrin did not biomagnify in this study as the reported BMFs are <1.0.	2533236
Bioaccumulation in biota sampled in the aquatic field	Capture 2EC (240 g bifenthrin/L formulation)	Estimated ranged of BAF:Catfish: 134 – 5385 Channel catfish: 77 – 12682 Gizzard shad: 499 – 12458 Threadfin shad: 182 – 1855 Redear sunfish: 51 – 3844 Spotted sucker: 535 – 11564 Bluegill sunfish: 11 – 7430 White crappie: 11 – 3430 Largemouth bass: 116 - 8715		1755966 1762382
Food web bioaccumulation modelling and risk assessment	Modelling	The risk via bioaccumulation was assessed with new data and modelling by EFSA. A food web bioaccumulation model, evaluated against field data for fish measured in agricultural settings after extensive bifenthrin applications, was applied using evaluative bioaccumulation and exposure assumptions. Time-dependent bioaccumulation and exposure calculations were determined by linking the output from a five-year FOCUS model scenario as input for the food web predictions. Bifenthrin is found in each level of the food chain but no biomagnification has been observed. There was no biomagnification into the highest trophic level (omnivorous fish) indicating that bifenthrin does not bioaccumulate over 5 years of simulated exposure. In addition, calculated TER values are greater than	A summary of the information reviewed by European Commission indicates that although bifenthrin is found in each level of the food chain, no biomagnification has been observed. (EC, 2010) However, concerns raised by the PRAPeR 87 experts' meeting indicated that the high risk from bioaccumulation through the food chain for aquatic organisms could not be excluded (EFSA, 2011).	2422597

Study	Test substance	Value		Comments	Reference
		the trigger when all acute fish toxicity endpoints were compared to estimates of aggregate fish residues based on combining all potential routes of exposure including dietary and environmental water sources.			
Field studies					
Field dissipation in an ecoregions not representative of Canadian conditions (Supplemental studies)	Capture 2EC (240 g bifenthrin/L formulation)	US Champaign Illinois	DT$_{50}$: 215 d DT$_{90}$: 714 d	Persistent	1762370
	Brigade 10WP (10% bifenthrin w/w)		DT$_{50}$: 86.7 d DT$_{90}$: 288 d	Moderately persistent	1762369
	Talstar SC (7.8% bifenthrin w/w)	European: Goch Germany Meynes France Budrio Italy	DT$_{50}$: 207 d DT$_{90}$: 687 d DT$_{50}$: 153 d DT$_{90}$: 507 d DT$_{50}$: 80 d DT$_{90}$: 264 d	Persistent Persistent Moderately persistent	1755908
Terrestrial field dissipation study in Canada	Bridgade 2EC (25.1% bifenthrin w/w)	Prince Edward Island	DT$_{50}$: 108 days DT$_{90}$: 288 days	Moderately persistent This study is classified as unreliable and does not fulfill the data requirement.	2533221
Field dissipation – cottonfield and outdoor pond study	Capture 2EC (240 g bifenthrin/L formulation)	US Dallas, Alabama	Cotton field DT$_{50}$: 197 d DT$_{90}$: 645 d Pont water DT$_{50}$: 609 days DT$_{90}$: not calculated	Persistent	1755966 1762383 1762384 1762387 1762385 1762380

Table 13 Name and chemical structure of environmental transformation products of bifenthrin

Code Name/ Synonym	Chemical Name	Chemical Structure
Major transformation product (>10%)		
Trans bifenthrin in aqueous photolysis study	cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-, (2-methyl[1,1'-biphenyl]-3-yl)methyl ester, trans- (9Cl)	 H$_3$C CH$_3$ Cl F F F O O Ph CH$_3$

Biphenyl alcohol BP-alcohol in aqueous photolysis study	2-methyl-3-phenylbenzyl alcohol 2-methyl-3-biphenyl methanol	
4'-hydroxy bifenthrin 4'-OH bifenthrin in laboratory aerobic water-sediment study	(4'-hydroxy-2-methyl-3-biphenyl)methyl (1RS, 3RS)-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylate	
TFP acid (*Cis* and *Trans*) in aquatic photolysis study	(1RS, 3RS)-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propen-1-yl]-2,2-dimethylcyclopropanecarboxylic acid	
Minor transformation products (<10%)		
Hydroxyl-methyl bifenthrin OH-methyl bifenthrin	(2-methyl-3-biphenyl)methyl (1RS, 3RS)-3-[(1Z)-2-chloro-3,3,3-trifuoro-1-propen-1-yl]-2-(hydroxymethyl)-2-methylcyclopropanecarboxylate	
Biphenyl aldehyde BP-aldehyde	2-methyl-3-phenylbenzyl aldehyde 2-methyl-3-biphenylcarbaldehyde	

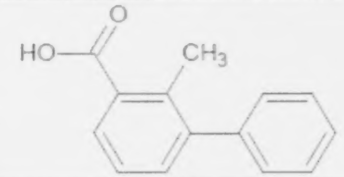
Code Name/ Synonym	Chemical Name	Chemical Structure
Biphenyl acid BP-acid	2-methyl-3-phenylbenzoic acid 2-methyl-3-biphenylcarboxylic acid	

Table 14 Summary of formation of transformation products (% applied radioactivity) formed in the submitted environmental studies

Study type				Maximum % AR (day)	Final %AR (study length)	Reference
Trans bifenthrin						
Soil photolysis		Cyclopropyl label		2.3 (30)	2.3 (30)	1755325
		Phenyl label		3.1 (30)	3.1 (30)	
Aqueous photolysis		Cyclopropyl label		36.7 (262)	36.7 (262)	1924824
		Phenyl label		48.9 (165)	30.4 (310)	
BP-alcohol						
Soil photolysis		Phenyl label		1.6 (30)	1.6 (30)	1755325
Aqueous photolysis				19.0 (211)	15.2 (310)	1924824
Aerobic soil	Silty clay			0.2% (120)	0.2% (120)	1755314 1755318 1755319 1755321
	Sandy loam			0.4% (120)	0.4% (120)	
	Silt loam (Dunkirk)			0.4% (120)	0.4% (120)	
	Silt loam (Georgetown)			0.4% (62-90)	0.2% (126)	1755315 1755322
Aerobic water-sediment	Calwich	Phenyl label	Water	1.1% (2)	NA (99)	1755309
			Sediment	0.6% (14-30)	0.1% (99)	
	Swiss lake		Water	1.3% (0)	NA (99)	
			Sediment	1.1 (99)	1.1 (99)	
4'-OH bifenthrin						
Soil photolysis		Cyclopropyl label		0.5 (14)	0.3 (30)	1755325
		Phenyl label		0.6 (14)	0.5 (30)	
Aerobic soil	Silty clay	Cyclopropyl label		1.0% (180)	1.0% (180)	1755314 1755318 1755319 1755321
		Phenyl label		3.3% (120)	3.3% (120)	
	Sandy loam	Cyclopropyl label		5.0% (180)	5.0% (180)	
		Phenyl label		4.1% (120)	4.1% (120)	
	Silt loam (Dunkirk)	Cyclopropyl label		3.7% (180)	3.7% (180)	
		Phenyl label		8.2% (120)	8.2% (120)	
	Silt loam (Georgetown)	Cyclopropyl label		3.8% (30)	2.5% (126)	1755315 1755322
		Phenyl label		3.6% (30)	3.6% (30)	
Aerobic water-sediment	Calwich	Cyclopropyl Label	Water	5.4% (0)	0 (1)	1755309
			Sediment	4.4% (99)	4.4% (99)	
		Phenyl Label	Water	1.9% (9)	NA (99)	
			Sediment	5.6% (99)	5.6% (99)	
	Swiss Lake	Cyclo-	Water	0.2% (14-30)	NA (99)	

Study type				Maximum % AR (day)	Final %AR (study length)	Reference
		propyl Label	Sediment	9.2% (99)	9.2% (99)	
		Phenyl Label	Water	0.3% (0)	NA (99)	
			Sediment	11.1% (99)	11.1% (99)	
TFP acid						
Soil photolysis		Cyclopropyl label		3.8 (30)	3.8 (30)	1755325
Aqueous photolysis				12.2 (262)	10.2 (262)	1924824
Aerobic soil	Silty clay			3.7% (180)	3.7% (180)	1755314 1755318 1755319 1755321
	Sandy loam			0.2% (180)	0.2% (180)	
	Silt loam (Dunkirk)			1.6% (180)	1.6% (180)	
	Silt loam (Georgetown)			0.8% (62)	0.5% (126)	1755315 1755322
Aerobic water-sediment	Calwich	Cyclo-propyl Label	Water	0.8% (30)	NA (99)	1755309
			Sediment	0.8% (14)	0.6% (99)	
	Swiss lake		Water	1.5% (30)	NA (99)	
			Sediment	0.9% (60)	0.3% (99)	
BP-aldehyde						
Soil photolysis				1.3 (30)	1.3 (30)	1755325
Aerobic soil	Silty clay	Phenyl label		0.2% (120)	0.2% (120)	1755314 1755318 1755319 1755321
BP-acid						
Soil photolysis				1.4 (14)	1.4 (30)	1755325
Aerobic soil	Silty clay	Phenyl label		0.6% (120)	0.6% (120)	1755314 1755318 1755319 1755321
	Sandy loam			1.7% (120)	1.7% (120)	
	Silt loam (Dunkirk)			0.5% (120)	0.5% (120)	
	Silt loam (Georgetown)			0.7% (126)	0.7% (126)	1755315 1755322
Aerobic water-sediment	Calwich	Phenyl label	Water	1.5% (28)	NA (99)	1755309
			Sediment	0.9 (30)	0.0 (99)	
	Swiss lake		Water	1.4% (14)	NA (99)	
			Sediment	0.9% (30)	0.0 (99)	
AR applied radioactivity NA not analyzed						

Table 15 Toxicity of bifenthrin, a formulated product and transformation products to Non-Target terrestrial Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
Invertebrates					
Earthworm (*E. fetida*)	14-day	Bifenthrin	14-d NOEC = 5.7 mg a.i./kg dw soil 14-d LOEC = 18.9 mg a.i./kg dw soil 14-d LC_{50} >18.9 mg a.i./kg dw soil	No classification	1755289
		Talstar 8 SC	14-d NOEC = 7.89 mg a.i./kg dw soil	No	1755918

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
			14-d LOEC = 14.0 mg a.i./kg dw soil 14-d LC_{50} >78.9 mg a.i./kg dw soil	classification	
	56-day reproduction	Talstar 8 SC	NOEC = 2.13 mg a.i./kg dw soil LOEC = 4.26 mg a.i./kg dw soil	No classification	1755920
		4'-OH bifenthrin	NOEC = 178 mg TP/kg dw soil LOEC = 316 mg TP/kg dw soil	No classification	1755186
		TFP acid	NOEC = 17.8 mg TP/kg dw soil LOEC = 31.6 mg TP/kg dw soil	No classification	
Bee	Acute Oral	Talstar 8 SC	NOEC < 0.09 µg a.i./bee LD_{50}=0.13 µg a.i./bee	Highly toxic	1755922
	Acute Contact		NOEC = 0.05 µg a.i./bee LD_{50}=0.07 µg a.i./bee	Highly toxic	
	Field aged residue	Capture 2 EC	RT_{25} = 1.2 to 2.2 DAA for 56 g a.i./ha 3.2-4.2 DAA for 112 g a.i./ha >5.2 DAA for 224 g a.i./ha	No classification	1755286
Ladybird beetle (*C. septempunctat L)*	Aged residue	Talstar 8 SC	% mortality in the 7.87 g a.i./ha × 2 treatment group was not statistically different from the control when exposed to 21-day old residue. % Mortality in the 50 g a.i./ha × 2 treatment group was not statistically different from the control when exposed to 35-day aged residue.	No classification	1755917
	Extended laboratory study		Exposure to treated apple leaves LR_{50} = 0.084 g a.i./ha (95% CI 0.055-0.105 g a.i./ha)	No classification	1755925
A. rhopalosiphi	Acute contact	Talstar 8 SC	24 hours old adults exposed to glass plates or maize leaves treated with 7.5 g a.i./ha had 100% mortality 2-3 days old mummified aphids treated with 7.5 g a.i./ha had comparable emergence rate and reproductive success as the control.	No classification	1755919
	Extended laboratory study		Exposure to treated barley seedlings LR_{50} = 8.145 g a.i./ha (95% CI 6.213-10.805 g a.i./ha)	No classification	1755926
	Aged residue		% mortality in the 1.6 g a.i./ha × 2 treatment group was not statistically different from the control when exposed to 7-day old residue. % Mortality in the 6.1 g a.i./ha × 2 treatment group was not statistically different from the control when exposed to 14-day aged residue. % Mortality in the 50 g a.i./ha × 2 treatment group was not statistically different from the control when exposed to 28-day aged residue.	No classification	1755921 1755927
Ground beetle *(P. cupreus L)*	Extended laboratory study	Talstar 8 SC	NOER based on mortality and food consumption was 0.1066 mg a.i./kg	No classification	1755923

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity	Reference
	Limit test				
Green lacewing (*C. carnea)*	Extended laboratory study	Talstar 8 SC	Exposure to treated bean leaves NOER = 2.279 g a.i./ha LR_{50} = 5.132 g a.i./ha (95% CI 1.952-7.151 g a.i./ha)	No classification	1755924
Predatory mite *(T. pyri)*	Extended laboratory study	Talstar 8 SC	Exposure to treated apple leaves NOER = 0.0009 g a.i./ha LR_{50} = 0.113 g a.i./ha (95% CI 0.091-0.143 g a.i./ha)	No classification	1755930
Birds					
Bobwhite quail	Acute oral	Bifenthrin	NOEL = 464 mg a.i./kg bw LD_{50} = 1800 mg a.i./kg bw	Slightly toxic	1755213
	5-d Dietary		NOEC = 2500 mg a.i./kg diet (NOEL = 393 mg a.i./kg bw/day) LC_{50} = 4450 mg a.i./kg diet (LD_{50} = 597 mg a.i./kg bw/day)	Slightly toxic	1755205
	24-week Reproduction		NOEC = 75 mg a.i./kg dw diet	No classification	1755200
Mallard duck	Acute oral		NOEL = 2150 mg a.i./kg bw $LD_{50} \geq 2150$ mg a.i./kg bw	Practically non-toxic	1755212
	5-d Dietary		NOEC <312 mg a.i./kg diet (NOEL < 104 mg a.i./kg bw/day) LC_{50} = 1222 mg a.i./kg diet LD_{50} was not calculated because of inconsistent food consumption	Slightly toxic	1755203
	22-week Reproduction		NOEC = 75 mg a.i./kg dw diet	No classification	1755199
Mammals					
Mouse Swiss Webster	Acute oral	Bifenthrin	LD_{50} (95% CI): ♂ = 43.5 mg/kg bw (36.2-50.7 mg/kg bw) ♀ = 42.5 mg/kg bw (37.1-47.9 mg/kg bw) Combined = 43.0 mg/kg bw	Highly toxic	1755501
Rat Sprague-Dawley	Multi-generation Reproduction	Bifenthrin	Repro LOAEL = 5 mg/kg bw/day Repro NOAEL = 3 mg/kg bw/day	No classification	1755448
Vascular plants					
Vascular plant	21d-Seedling emergence	Talstar 8 SC	NOEC = 0.08 g a.i./kg dw soil	No classification	1755192

Table 16 Screening level risk assessment for bifenthrin and transformation products on non-target terrestrial species other than birds and mammals

Organism	Exposure	Endpoint value	EEC	RQ	Level of concern
Invertebrates					
Earthworm	Acute	$LC_{50}/2$ = 9.5 mg a.i./kg soil	0.150 mg a.i./kg dw soil	0.02	Not exceeded
	Chronic	NOEC = 2.13 mg a.i./kg dw soil	0.150 mg a.i./kg dw soil	0.07	Not exceeded
Bee	Acute oral	LD_{50} = 0.13 µg a.i./bee	0.269 µg a.i./bee	2.1	Exceeded
	Acute	LD_{50} = 0.07 µg a.i./bee	6.96 µg a.i./bee	99	Exceeded

Organism	Exposure	Endpoint value	EEC	RQ	Level of concern
	contact				
A. rhopalosiphi (aphid parasitoid) Foliar dwelling parasite	Acute contact	LR_{50}< 7.5 g a.i./ha	In-field: 126 g a.i./ha	In-field: >17	Exceeded
			Off-field: 74.3 g a.i./ha	Off-field: >10	Exceeded
C. septempunctat L. (ladybird beetle) Foliar dwelling predator	Extended laboratory study Contact	LR_{50} = 0.084 g a.i./ha	In-field: 126 g a.i./ha	In-field: 1500	Exceeded
			Off-field: 74.3 g a.i./ha	Off-field: 885	Exceeded
A. rhopalosiphi (aphid parasitoid) Foliar dwelling parasite		LR_{50} = 8.145 g a.i./ha	In-field: 126 g a.i./ha	In-field: 15	Exceeded
			Off-field: 74.3 g a.i./ha	Off-field: 9	Exceeded
P. cupreus L (carabid beetle) Soil dwelling predator		NOER = 0.1066 mg a.i./kg dw soil	In-field: 0.09 mg a.i./kg dw soil	In-field: 0.84	Not exceeded
C. carnea (green lacewing) Foliar dwelling predator		LR_{50} = 5.132 g a.i./ha	In-field: 126 g a.i./ha	In-field: 25	Exceeded
			Off-field: 74.3 g a.i./ha	Off-field: 14	Exceeded
T. pyri (predatory mite) Foliar dwelling predator		LR_{50} = 0.113 g a.i./ha	In-field: 126 g a.i./ha	In-field: 1115	Exceeded
			Off-field: 74.3 g a.i./ha	Off-field: 658	Exceeded
Vascular plants					
Vascular plant	Seedling emergence	NOEC = 0.08 mg a.i./kg dw soil EC25 > 0.08 mg a.i./kg dw soil	Potato: 0.150 mg a.i./kg dw soil Raspberry: 0.094 mg a.i./kg dw soil	< 1.9 < 1.175	Exceeded*

* Even though the LOC is slightly exceeded, effects on terrestrial plants are not expected given that no adverse effects were observed in six species of non-target terrestrial plants at the highest dose tested.

Table 17 Refined risk assessments on terrestrial non-target arthropods

Organism	Endpoint value	EEC	RQ	Level of concern
C. septempunctat L. (ladybird beetle) Foliar dwelling predator	LR_{50} = 0.084 g a.i./ha	In-field: 101 g a.i./ha	In-field: 1202	Exceeded
		Off field: 7.43 g a.i./ha	Off-field: 88.5	Exceeded
A. rhopalosiphi (aphid parasitoid) Foliar dwelling parasite	LR_{50} = 8.145 g a.i./ha	In-field: 101 g a.i./ha	In-field: 12	Exceeded
		Off-field: 7.43 g a.i./ha	Off-field: 0.9	Not exceeded
C. carnea (green lacewing) Foliar dwelling predator	LR_{50} = 5.132 g a.i./ha	In-field: 101 g a.i./ha	In-field: 20	Exceeded
		Off-field: 7.43 g a.i./ha	Off-field: 1.4	Exceeded
T. pyri (predatory mite) Foliar dwelling predator	LR_{50} = 0.113 g a.i./ha	In-field: 101 g a.i./ha	In-field: 894	Exceeded
		Off-field: 7.43 g a.i./ha	Off-field: 7.43	Exceeded

Table 18 Screening level risk assessment on birds and mammals

Organism	Toxicity (mg a.i./kg bw/d)[1]	Feeding Guild (food item)	EDE (mg a.i./kg bw)[2]	RQ	Level of Concern
Small Bird (0.02 kg)					
Acute	180	Insectivore (small insects)	6.35	0.04	Not exceeded
Reproduction	6.71	Insectivore (small insects)	6.35	0.95	Not exceeded
Medium-Sized Bird (0.1 kg)					
Acute	180	Insectivore (small insects)	4.95	0.03	Not exceeded
Reproduction	6.71	Insectivore (small insects)	4.95	0.74	Not exceeded
Large-Sized Bird (1 kg)					
Acute	180	Herbivore (short grass)	5.17	0.03	Not exceeded
Reproduction	6.71	Herbivore (short grass)	5.17	0.77	Not exceeded
Small Mammal (0.015 kg)					
Acute	4.30	Insectivore (small insects)	3.65	0.85	Not exceeded
Reproduction	3	Insectivore (small insects)	3.65	1.22	Exceeded
Medium-Sized Mammal (0.035 kg)					
Acute	4.3	Herbivore (short grass)	11.44	2.66	Exceeded
Reproduction	3	Herbivore (short grass)	11.44	3.81	Exceeded
Large-Sized Mammal (1 kg)					
Acute	4.3	Herbivore (short grass)	6.11	1.42	Exceeded
Reproduction	3	Herbivore (short grass)	6.11	2.04	Exceeded

[1] Toxicity values for the acute exposure have been adjusted with an uncertainty factor of 0.1.

[2] EDE = Estimated dietary exposure; is calculated using the following formula: (FIR/BW) × EEC, where:

FIR: Food Ingestion Rate (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:

Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$

All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{BW in g})^{0.651}$.

For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{BW in g})^{0.822}$

BW: Generic Body Weight

EEC: Concentration of pesticide on food item based on Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994). At the screening level, relevant food items representing the most conservative EEC for each feeding guild are used.

Table 19 Expanded risk assessment on mammals

Organism/ Toxicity	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues	
		On-field		Off-Field		On-field	
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
Small Mammal (0.015 kg)							
Reproduction 3.00 mg a.i./kg bw/d	Insectivore (small insects)	3.65	**1.2**	2.15	0.72	2.04	0.68
	Granivore (grain and seeds)	0.91	0.30	0.54	0.18	0.44	0.15
	Frugivore (fruit)	1.83	0.61	1.08	0.36	0.87	0.29
Medium Sized Mammal (0.035 kg)							
Acute 4.30 mg a.i./kg bw/d	Insectivore (small insects)	3.20	0.74	1.89	0.43	1.79	0.42
	Insectivore (large insects)	0.80	0.19	0.47	0.11	0.38	0.09
	Granivore (grain and seeds)	0.80	0.19	0.47	0.11	0.38	0.09
	Frugivore (fruit)	1.60	0.37	0.94	0.22	0.76	0.18
	Herbivore (short grass)	11.44	**2.66**	6.75	**1.57**	4.06	0.94

Organism/ Toxicity	Food Guild (food item)	Maximum nomogram residues				Mean nomogram residues	
		On-field		Off-Field		On-field	
		EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ	EDE (mg a.i./kg bw)	RQ
	Herbivore (long grass)	6.99	**1.62**	4.12	0.96	2.28	0.53
	Herbivore (forage crops)	10.59	**2.46**	6.25	**1.45**	3.50	0.81
Reproduction 3.00 mg a.i./kg bw/d	Insectivore (small insects)	3.20	**1.07**	1.89	0.63	1.79	0.60
	Insectivore (large insects)	0.80	0.27	0.47	0.16	0.38	0.13
	Granivore (grain and seeds)	0.80	0.27	0.47	0.16	0.38	0.13
	Frugivore (fruit)	1.60	0.53	0.94	0.31	0.76	0.25
	Herbivore (short grass)	11.44	**3.81**	6.75	**2.25**	4.06	**1.35**
	Herbivore (long grass)	6.99	**2.33**	4.12	**1.38**	2.28	0.76
	Herbivore (forage crops)	10.59	**3.53**	6.25	**2.08**	3.50	**1.17**
Large Sized Mammal (1 kg)							
Acute 4.30 mg a.i./kg bw/d	Insectivore (small insects)	1.71	0.40	1.01	0.23	0.95	0.22
	Insectivore (large insects)	0.43	0.10	0.25	0.06	0.20	0.05
	Granivore (grain and seeds)	0.43	0.10	0.25	0.06	0.20	0.05
	Frugivore (fruit)	0.86	0.20	0.50	0.12	0.41	0.09
	Herbivore (short grass)	6.11	**1.42**	3.61	0.84	2.17	0.50
	Herbivore (long grass)	3.73	0.87	2.20	0.51	1.22	0.28
	Herbivore (forage crops)	5.66	**1.32**	3.34	0.78	1.87	0.43
Reproduction 3.00 mg a.i./kg bw/d	Insectivore (small insects)	1.71	0.57	1.01	0.34	0.95	0.32
	Insectivore (large insects)	0.43	0.14	0.25	0.08	0.20	0.07
	Granivore (grain and seeds)	0.43	0.14	0.25	0.08	0.20	0.07
	Frugivore (fruit)	0.86	0.29	0.50	0.17	0.41	0.14
	Herbivore (short grass)	6.11	**2.04**	3.61	**1.20**	2.17	0.72
	Herbivore (long grass)	3.73	**1.24**	2.20	0.73	1.22	0.41
	Herbivore (forage crops)	5.66	**1.89**	3.34	**1.11**	1.87	0.62

Table 20 Toxicity of bifenthrin, formulated products and transformation products to aquatic species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
Freshwater species					
D. magna	48hr-Acute	Bifenthrin	NOEC < 0.025 µg a.i./L LOEC = 0.025 µg a.i./L LC_{50} = 0.118 µg a.i./L	Very highly toxic	1755275
		Talstar 80g/l flowable	NOEC = 3.2µg a.i./L LOEC = 5.6 µg a.i./L LC_{50} = 5.7 µg a.i./L	Very highly toxic	1762399
	21d-Chronic	Bifenthrin	NOEC =0.0013 µg a.i./L LOEC = 0.0029 µg a.i./L	No classification	1755269
C. riparius	Water spiked	Bifenthrin	NOEC = 0.32 µg a.i./L LOEC = 1.0 µg a.i./L EC_{50} = 3.96 µg a.i./L	Very highly toxic	1755267
	Sediment spiked		NOEC = 40 µg a.i./kg dw sediment LOEC = 126 µg a.i./kg dw sediment EC_{50} = 345.5 µg a.i./kg dw sediment	No classification	1755279

Organism	**Exposure**	**Test substance**	**Endpoint value**	**Degree of toxicity[1]**	**Reference**
	Sediment spiked	4'-OH bifenthrin	NOEC = 1.581 mg TP/kg dw sediment LOEC = 5.000 mg TP/kg dw sediment EC_{50} = 3.593 mg TP/kg dw sediment	No classification	1755277
Rainbow trout *(O. mykiss)*	96hr-Acute	Bifenthrin	NOEC = 0.03 µg a.i./L LOEC = 0.08 µg a.i./L LC_{50} = 0.10µg a.i./L	Very highly toxic	1755251
			NOEC = 0.0948 µg a.i./L LC_{50} = 0.256 µg a.i./L	Very highly toxic	2533229
			Bifenthrin residues in fish sampled from the 0.0948 µg a.i./L treatment group: 137±18.1 µg a.i./kg Bifenthrin residues in fish sampled from 0.322 µg a.i./L treatment group: 546 ± 9.76 µg a.i./kg	N/A	2533230
		4'-OH bifenthrin	NOEC = 0.805 µg TP/L LC_{50} = 3.9µg TP/L	Very highly toxic	1755252
		TFP acid	NOEC = 2.8 mg TP/L LOEC = 6.2 mg TP/L LC_{50} = 24.5 mg TP/L	Highly toxic	1755254
		Talstar 80g/L Flowable	NOEC = 0.01 mg a.i./L LOEC = 0.018 mg a.i./L LC_{50} = 0.030 mg a.i./L	Very highly toxic	1759123
Bluegill sunfish *(L. macrochiru)*	96hr-Acute	Bifenthrin	NOEC = 0.10 µg a.i./L LOEC = 0.13 µg a.i./L LC_{50} = 0.26µg a.i./L	Very highly toxic	1755246
			NOEC = 0.209 µg a.i./L LC_{50} = 0.269 µg a.i./L	Very highly toxic	2533231
			Bifenthrin residues in fish sampled from the 0.209 µg a.i./L treatment group: 196 ± 5.74 µg a.i./kg Bifenthrin residues in fish sampled from 0.346 µg a.i./L treatment group: 625 ± 121 µg a.i./kg		2533230
Fathead minnow	96hr-Acute	Bifenthrin	NOEC =0.083µg a.i./L LOEC = 0.17 µg a.i./L LC_{50} = 0.21µg a.i./L	Very highly toxic	1755227
			LC_{50} = 0.234µg a.i./L	Very highly toxic	2533232
	Full life cycle		NOEC =0.04 µg a.i./L LOEC = 0.09 µg a.i./L	No classification	1755227
Medaka (*O. latipes*)	96hr-Acute	Bifenthrin	LC_{50} = 1.77 g a.i./L	Very highly toxic	2533233
Common carp (*C. carpio*)	96hr-Acute	Bifenthrin	LC_{50} = 0.635 µg a.i./L	Very highly toxic	2533234
Zebra fish (*B. rerio*)	96hr-Acute	Bifenthrin	LC_{50} = 1.965 µg a.i./L	Very highly toxic	2533235
Green alga *(D. subspicatus)*	72hr-limit test	Talstar 8 SC	NOEC = 6.3 mg a.i./L (100 mg EP/L)	No classification	1755945

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[1]	Reference
			LC_{50} > 6.3 mg a.i./L		
Mesocosm	Phytoplankton	Talstar 80 Flowable	NOEC =0.935 µg a.i./L**	No classification	1755962
	Macrophyte		NOEC =0.935 µg a.i./L*		
	Zooplankton		NOEC =0.001 µg a.i./L* LOEC = 0.005 µg a.i./L*		
	Macroinvertebrate		NOEC =0.005 µg a.i./L* LOEC = 0.015 µg a.i./L*		
	Taxonomic richness		NOEC =0.015 µg a.i./L* LOEC = 0.037 µg a.i./L*		
Marine species					
Mysids *(A. bahia)*	96hr-Acute	Bifenthrin	NOEC <0.00248 µg a.i./L LOEC = 0.00248 µg a.i./L LC_{50} = 0.00397µg a.i./L	Very highly toxic	1755262
	28d-Chronic	Bifenthrin	NOEC = 0.0012 µg a.i./L LOEC = 0.0013 µg a.i./L LC_{50} = 0.00226 µg a.i./L	No classification	1755258
Eastern Oyster *(C. virginica)*	48hr-Acute embryo	Bifenthrin	NOEC = 0.126g mg a.i./L LOEC = 0.448 mg a.i./L EC_{50} = 0.280 mg a.i./L	Highly toxic	1755261
	96hr-Acute shell deposition	Bifenthrin	NOEC = 1.09 µg a.i./L LOEC = 2.15 µg a.i./L EC_{50} >2.15 µg a.i./L	Very highly toxic	1755260
Sheepshead minnow *(C. variegatus)*	96hr-Acute	Bifenthrin	NOEC = 10.9 µg a.i./L LC_{50} = 17.53 µg a.i./L	Very highly toxic	1755242

[1] USEPA classification, where applicable

* Based on nominal treatment concentration of one application.

** Increased abundance was observed at 0.037 µg a.i./L and was not considered as adverse effect. Therefore, the highest treatment level was the NOEC.

Table 21 Screening level risk assessment of bifenthrin to aquatic organisms

Organism	Exposure	Endpoint value	EEC***	RQ	LOC
Freshwater species					
D. magna	Acute	$LC_{50}/2$ = 0.059 µg a.i./L	27 µg a.i./L	458	Exceeded
	Chronic	NOEC = 0.0013 µg a.i./L		20,770	
C. riparius	Water spiked	$EC_{50}/2$ = 1.98 µg a.i./L		14	
Freshwater invertebrates SSD	Acute	HC_5 = 0.009 µg a.i./L		3000	
Rainbow trout	Acute	$LC_{50}/10$ = 0.01 – 0.0256 µg a.i./L		1055 - 2700	
Bluegill sunfish	Acute	$LC_{50}/10$ = 0.026 - 0.027 µg a.i./L		1000 - 1038	
Fathead minnow	Acute	$LC_{50}/10$ = 0.021 – 0.023 µg a.i./L		1174 - 1286	
	Chronic	NOEC = 0.04 µg a.i./L		675	
Medaka *(O. latipes)*	Acute	$LC_{50}/10$ = 0.177 µg a.i./L		153	
Common carp	Acute	$LC_{50}/10$ = 0.064 µg a.i./L		422	

Organism	Exposure	Endpoint value	EEC[***]	RQ	LOC
(*C. carpio*)					
Zebra fish (*B. rerio*)	Acute	LC$_{50}$/10 = 0.197 µg a.i./L		137	
Freshwater fish SSD	Acute	HC$_5$ = 0.078 µg a.i./L		346	
Green algae	Acute	EC$_{50}$ /2>3150 µg a.i./L	27 µg a.i./L	<0.01	Not exceeded
Amphibian	Acute[*]	Fish HC$_{05}$ = 0.078 µg a.i./L	144 µg a.i./L	1846	Exceeded
	Chronic[**]	NOEC = 0.04 µg a.i./L		3600	
Marine species					
Mysid *A. bahia*	Acute	LC$_{50}$/2 = 0.00199 µg a.i./L	27 µg a.i./L	13602	Exceeded
	Chronic	NOEC = 0.0012 µg a.i./L		22500	
Eastern oyster	Acute embryo	LC$_{50}$/2 = 140 µg a.i./L	27 µg a.i./L	0.2	Not exceeded
	Acute shell deposition	EC$_{50}$/2 > 1.08 µg a.i./L	27 µg a.i./L	<25	Exceeded
Sheepshead minnow	Acute	LC$_{50}$/10 = 1.753 µg a.i./L	27 µg a.i./L	15	Exceeded

[*] Rainbow trout data was used as surrogate.

[**] Fathead minnow full life cycle data was used as surrogate.

[#] The NOEC was the highest treatment concentration.

[***] EEC based on a 15 cm water body depth for amphibians and an 80 cm water depth for all other aquatic organisms.
Bolded values indicates an exceedance of the level of concern (RQ = 1).

Table 22 Off-field risk assessment of bifenthrin to aquatic organisms from spray drift

Organism	Exposure	Endpoint value	EEC[***]	RQ	LOC
Freshwater species					
Freshwater invertebrates SSD	Acute	HC$_5$ = 0.009 µg a.i./L	16 µg a.i./L	1778	Exceeded
Freshwater Invertebrates mesocosm – Taxonomic richness	Chronic	NOEC/3 = 0.005 µg a.i./L		3000	
Fathead minnow	Chronic	NOEC = 0.04 µg a.i./L		400	
Freshwater fish SSD	Acute	Fish HC$_5$ = 0.078 µg a.i./L		205	
Amphibian	Acute	Fish HC$_5$ = 0.078 µg a.i./L	85 µg a.i./L	1090	
	Chronic	NOEC = 0.04 µg a.i./L		2125	
Marine species					
Mysid *A. bahia*	Acute	LC$_{50}$/2 = 0.001985 µg a.i./L	16 µg a.i./L	8060	Exceeded
	Chronic	NOEC = 0.0012 µg a.i./L		13333	
Eastern oyster	Acute shell deposition	EC$_{50}$/2 = 1.08 µg a.i./L		15	
Sheepshead minnow	Acute	LC$_{50}$/10 = 1.753 µg a.i./L		9	

[***] The EEC values were based on a 15 cm water depth for amphibians and a 80 cm water depth for all other aquatic organisms. The spray drift exposure was determined by assuming 59% drift from a later season airblast application on raspberries. The estimated EEC values were higher than the theoretical solubility.
Bolded values indicates an exceedance of the level of concern (RQ = 1).

Table 23 Off-field risk assessment of bifenthrin to aquatic organisms from predicted runoff excluding spray drift

Organism	Exposure	Endpoint value	EEC (µg a.i./L)	RQ	LOC
Freshwater species					
Freshwater invertebrates SSD	Acute	HC_5 = 0.009 µg a.i./L	5.2[1]	578	Exceeded
Fathead minnow	Chronic	NOEC = 0.04 µg a.i./L	0.19[5]	5	Exceeded
Freshwater fish SSD	Acute	Fish HC_5 = 0.078 µg a.i./L	0.41[4]	5	
Amphibian	Acute	Fish HC_5 = 0.078 µg a.i./L	1.4[6]	18	
	Chronic	NOEC = 0.04 µg a.i./L	0.21[7]	5	
Mesocosm – Taxonomic richness	Chronic	NOEC/3 = 0.005 µg a.i./L	0.19[5]	38	Exceeded
Marine species					
Mysid *A. bahia*	Acute	$LC_{50}/2$ = 0.001985 µg a.i./L	0.41[4]	207	Exceeded
	Chronic	NOEC = 0.0012 µg a.i./L	0.25[2]	208	
Eastern oyster	Acute shell deposition	$EC_{50}/2$ = 1.08 µg a.i./L	0.41[4]	0.38	Not exceeded
Sheepshead minnow	Acute	$LC_{50}/10$ = 1.753 µg a.i./L		0.23	

[1] Acute EEC for *D. magna* was based on the highest detection of bifenthrin out of all surface water samples collected.
[2] Chronic EEC for *D. magna* and *A. bahia* was based on the 90th percentile of the 21 day average for 80 cm deep water body.
[4] Acute EEC for fish and marine species was based on the 90th percentile of the 96 hour average for 80 cm deep water body
[5] Chronic EEC for fathead minnow was based on the 90th percentile of the yearly average for 80 cm deep water body
[6] Acute EEC for amphibian was based on the 90th percentile of the 96 hour average for 15 cm deep water body
[7] Chronic EEC for amphibian was based on the 90th percentile of the yearly average for 15 cm deep water body

Table 24 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Bifenthrin Assessment against criteria
CEPA toxic or CEPA toxic equivalent	A substance is CEPA toxic (or CEPA toxic equivalent) if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health.	Yes: Bifenthrin meets the criteria under paragraph 64 (a) of CEPA and should be considered CEPA-toxic equivalent.
Predominantly anthropogenic	The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human	Yes: All releases to the environment are anthropogenic.

TSMP Track 1 Criteria	**TSMP Track 1 Criterion value**		**Bifenthrin Assessment against criteria**
	activity, rather than to natural sources or releases.		
Persistence[1]:	Soil	Half-life $\geq$ 182 days	Yes: Laboratory aerobic soil half-life: 78.7 to 203 days Field dissipation study half-life: 80-215 days
	Whole system (Water + sediment)	Half-life $\geq$ 182 days (water) Half-life $\geq$ 365 days (sediment)	Yes: Aerobic water sediment whole system half-life: 92.9 to 276 days
	Air	Half-life $\geq$ 2 days or evidence of long range transport	Not determined
	Other	In an aquatic field study conducted in Alabama, bifenthrin residues in the pond sediment persisted for two years after the last application. This was possibly due to its persistence in soil and the continuous input into the pond from runoff for the two years following the last application. Variability in sediment and water concentrations was high at each sample date, but this is common in field studies and should not be considered as detrimental to assessing the overall lack of decline of residues over time in the aquatic system. In addition, the monitoring data collected for sediment does lend relevance to the persistence observed in the laboratory study results, as bifenthrin was frequently detected in sediment samples collected in agricultural areas in the US (USGS NAWQA, PMRA 2398587).	
	Conclusion: The persistence criterion is met in: soil, water, sediment and aquatic systems. The environmental fate and persistence of bifenthrin is well characterized. It is acknowledged that the range in half-lives includes values below and above the TSMP criteria, however under most environmental conditions, bifenthrin is considered persistent. Long-range atmospheric transport cannot be determined at this time. The AOPWIN model is not suited for predicting the atmospheric half-life of bifenthrin given the large fraction expected to be sorbed to airborne particles.		
Bioaccumulation[2]	Log $K_{OW} \geq 5$	log *K*ow = 8.0 at 20°C (PMRA 1755525) log *K*ow = 6.4 (EPA 2010, cited from Laskowski 2002) log *K*ow = 6.6 (EFSA 2011)	
	BCF[3] $\geq$ 5000	Results of submitted laboratory studies: • Bluegill sunfish: $BCF_{K,GL}$ of 3400 - 3511; BCF_K of 5250 to 12,850 Carp: BCF_K of 1265 - 1861 • Fathead minnow adult: BCF_{SS} : 21,000 to 30,000	

TSMP Track 1 Criteria	**TSMP Track 1 Criterion value**	**Bifenthrin Assessment against criteria**
	$BMF^{4,5} \geq 1$	Dietary biomagnification study (bluegill sunfish): $BMF_{K,G,L}$: 0.28 Half-life in fish: 20 days Assimilation efficiency, α: 0.039 The study indicates that dietary uptake of bifenthrin did not contribute significantly to biomagnification as the reported BMF values are <1.0.
	BAF ≥ 5000	Field studies: Under field conditions when biota are exposed through multiple pathways, bioaccumulation occurs as was observed in various fish species under field conditions in the Alabama pond study: Catfish: BAF of 134 – 5385 Channel catfish: BAF of 77 – 12682 Gizzard shad: BAF of 499 – 12458 Threadfin shad: BAF of 182 – 1855 Redear sunfish: BAF of 51 – 3844 Spotted sucker: BAF of 535 – 11564 Bluegill sunfish: BAF of 11 – 7430 White crappie: BAF of 11 – 3430 Largemouth bass: BAF of 116 - 8715
	Other	A field monitoring study of dolphins from the Brazilian coast detected bifenthrin residues in liver, breast milk, and placental samples (Alonso *et al.*, 2012). The results of this study provide evidence of exposure and accumulation of bifenthrin in marine mammals and maternal transfer by both gestational and lactation pathways in non-agricultural areas.
	Conclusion: The bioaccumulation potential of bifenthrin is well characterized based on the information provided. Sufficient information was provided to show that bifenthrin BCFs are > 5000 in some fish species. One study showed that bifenthrin does not biomagnify in fish when only considering the diet under laboratory conditions (BMFs are <1.0). Under field conditions, however, sufficient information was provided to show that bifenthrin BAFs > 5000 are sustained long after applications. BMF conclusions have been integrated into the bioaccumulation summary in the monograph along with all other lines of evidence. BMF <1 should not supersede BCF/BAFs. The field BAF values are a better representation of bioaccumulation under environmentally relevant conditions and consider multiple pathways of exposure.	
[1] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met. [2] Field data (e.g., BAFs) are preferred over laboratory data (e.g., BCFs) which, in turn, are preferred over		

TSMP Track 1 Criteria	TSMP Track 1 Criterion value	Bifenthrin Assessment against criteria
chemical properties (e.g., log K_{OW}). [3] BCF_K : kinetic BCF; $BCF_{K,G,L}$: kinetic BCF corrected for growth and lipid content; BCF_{SS}: steady state BCF [4] $BMF_{K,G,L}$: kinetic BMF corrected for growth and lipid content [5] Biomagnification results from the processes of bioaccumulation and bioconcentration by which tissue concentrations of bioaccumulated substances increase as they are passed up through two or more trophic levels. The term implies an efficient transfer from food to consumer, so that residue concentrations increase systematically from one trophic level to the next. The extent of biomagnification is also influenced by several factors – the substance being accumulated, the number of stages in the food web, the kind of organisms in the food web, the ability of these organisms to metabolize the substance, the concentration of the substance at each level of the web, etc. (Government of Canada, 1995)		

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2.0 Human and Animal Health

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